INTERNATIONAL STANDARD

ISO 80601-2-79

First edition
2018-07

Medical electrical equipment —

Part 2-79:
Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment

Appareils électromédicaux —

Partie 2-79: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas de trouble ventilatoire

Reference number
ISO 80601-2-79:2018(E)

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

ISO 80601-2-79 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-79, in combination with ISO 80601-2-80[1] [1], cancels and replaces ISO 10651-6:2004[2]. This edition of ISO 80601-2-79 constitutes a major technical revision of ISO 10651-6:2004 and includes an alignment with the third edition of IEC 60601-1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-8 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

— splitting the scope of ISO 10651-6:2004[2] into two parts:

  — one for VENTILATORY IMPAIRMENT, also known as RESPIRATORY IMPAIRMENT, (this document) and

  — one for VENTILATORY INSUFFIENCY, also known as RESPIRATORY INSUFFICIENCY (ISO 80601-2-80);

— extending the scope to include the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, and thus not the VENTILATORY SUPPORT EQUIPMENT itself;

— identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

— tests for ventilation performance;

[1] Numbers in square brackets refer to the Bibliography.

— tests for mechanical strength (via IEC 60601-1-11);

— new symbols;

— requirements for VENTILATORY SUPPORT EQUIPMENT as a component of an ME SYSTEM;

— tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);

— tests for CLEANING and DISINFECTION PROCEDURES (via IEC 60601-1-11);

— consideration of contamination of the breathing gas delivered to the PATIENT from the GAS PATHWAYS.

Introduction

This document specifies requirements for VENTILATORY SUPPORT EQUIPMENT that is intended for use in the HOME HEALTHCARE ENVIRONMENT for PATIENTS who are not dependent on ventilation for their life support. VENTILATORY SUPPORT EQUIPMENT is frequently used in locations where SUPPLY MAINS is not reliable. VENTILATORY SUPPORT EQUIPMENT is often supervised by non-healthcare personnel (LAY OPERATORS) with varying levels of training. VENTILATORY SUPPORT EQUIPMENT complying with this document can be used elsewhere (i.e. in healthcare facilities).

Ventilatory support is often needed for PATIENTS who have stable ventilatory needs. This document addresses PATIENTS who have significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the PATIENT. This is best characterized by lung functions not worse than[3]:

— FEV_1/FVC[2] < 70 %; or

— 50 % ≤ FEV_1 < 80 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilation support are

— mild to moderate Chronic Obstructive Pulmonary Disease (COPD);

— neuromuscular/ amyotrophic lateral sclerosis (ALS);

— obese PATIENTS Obese Hypoventilation Syndrome (OHS);

— Cheyne–Stokes respiration (CSR/CSA).

CSR/CSA is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnoea. The pattern repeats, with each cycle usually taking 30 s to 2 min.

Cardiac PATIENTS with CSR/CSA might be breathless without having significant reduction in FEV_1. Reducing the work of breathing can help normalize their breathing.

This VENTILATORY SUPPORT EQUIPMENT is intended for PATIENTS who are spontaneously breathing and do not require ventilation for life support or intermittent periods of ventilation to maintain vital signs. VENTILATORY SUPPORT EQUIPMENT intended for this group of PATIENTS typically does not require PHYSIOLOGICAL ALARM CONDITIONS as no ESSENTIAL PERFORMANCE exists. These PATIENTS can gain adequate relief from fatigue related to the work of breathing by using VENTILATORY SUPPORT EQUIPMENT during the night and while taking breaks during the day. This can enable a PATIENT with VENTILATORY IMPAIRMENT to continue to move about and participate in the activities of daily living. Non-TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

— Requirements and definitions: roman type;

[2] This is also known as the Tiffeneau-Pinelli index.

— *Test specifications: italic type*;

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type; normative text of tables is also in a smaller type;

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD[3], IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of documents

[3] The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Medical electrical equipment

Part 2-79: Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1, applies, except as follows:

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, for VENTILATORY IMPAIRMENT, as defined in 201.3.202, hereafter also referred to as ME EQUIPMENT, in combination with its ACCESSORIES:

— intended for use in the HOME HEALTHCARE ENVIRONMENT;

— intended for use by a LAY OPERATOR; and

— intended for use with PATIENTS who have VENTILATORY IMPAIRMENT, the most fragile of these PATIENTS, would not likely experience injury with the loss of this artificial ventilation; and

— not intended for PATIENTS who are dependent on artificial ventilation for their immediate life support.

EXAMPLE 1 PATIENTS with mild to moderate chronic obstructive pulmonary disease (COPD).

NOTE 1 In the HOME HEALTHCARE ENVIRONMENT, the SUPPLY MAINS is often not reliable.

NOTE 2 Such VENTILATORY SUPPORT EQUIPMENT can also be used in non-critical care applications of professional health care facilities.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to the BREATHING SYSTEM of VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT.

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, DISTRIBUTED ALARM SYSTEM.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for:

— VENTILATORS or ACCESSORIES for VENTILATOR-DEPENDENT PATIENTS intended for critical care applications, which are given in ISO 80601-2-12;

— VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in ISO 80601-2-13[4];

— VENTILATORS or ACCESSORIES intended for the emergency medical services environment, which are given in ISO 80601-2-84 [5] 4, the future replacement for ISO 10651-3[6];

— VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT, which are given in ISO 80601-2-72;

— VENTILATORY SUPPORT EQUIPMENT or ACCESSORIES intended for VENTILATORY INSUFFICIENCY, which are given in ISO 80601-2-80[1];

— sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70[7];

— continuous positive airway pressure (CPAP) ME EQUIPMENT;

— high-frequency jet VENTILATORS (HFJVs);

— high-frequency oscillatory VENTILATORS (HFOVs)[8];

— oxygen therapy constant flow ME EQUIPMENT;

— cuirass or "iron-lung" ventilation equipment.

This document is a document in the IEC 60601 and IEC/ISO 80601 series of documents.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the VENTILATORY SUPPORT EQUIPMENT and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT.

4 Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, and IEC 60601-1-11:2015 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3[26] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx", where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

IEC 60601-1:2005+AMD1:2012, Clause 2, applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010[5], Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability *+Amendment 1:2013*+Amendment 1:2013

IEC 60601-1-8:2006[6], *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*+Amendment 1:2012

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[5] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

[6] There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-12:—[7], *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-72:2015, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005[8], Medical electrical equipment — Part 1: General requirements for basic safety and essential performance *+Amendment 1:2012*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

[7] To be published. Stage at time of publication ISO/FDIS 80601-2-12:2018.

[8] There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 7396-1:2016, ISO 8836:2014, ISO 9000:2015, ISO 9360-1:2000, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-11:2015, IEC 62366-1:2015, ISO 80601-2-12:—, ISO 80601-2-72:2015, ISO 80601-2-74:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found Annex DD.

201.3.201

HEALTHCARE PROFESSIONAL

term referring to an individual with relevant specialized training, knowledge and skills who provides preventive, curative, promotional or rehabilitative health care services in a systematic way to people, families or communities

EXAMPLE HEALTHCARE PROFESSIONAL OPERATOR.

Note 1 to entry: The HEALTHCARE PROFESSIONAL OPERATOR is the supervising clinician or the HEALTHCARE PROFESSIONAL responsible for the treatment of a PATIENT on VENTILATORY SUPPORT EQUIPMENT.

[SOURCE: ISO 80601-2-12:—, definition 201.3.210, modified — added note.]

201.3.202

VENTILATORY IMPAIRMENT

RESPIRATORY IMPAIRMENT

clinically significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the PATIENT

Note 1 to entry: PATIENTS with VENTILATORY IMPAIRMENT exhibit a minimal level of illness acuity, fragility, or instability. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange is minimal. Without such support as needed, these PATIENTS would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. Without ventilatory support as needed, these PATIENTS are likely to experience short periods of abnormal lung gas exchange which can result in them becoming more sedentary.

EXAMPLE PATIENTS with mild to moderate chronic obstructive pulmonary disease (COPD).

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT is suitable for use where PHYSIOLOGICAL ALARM CONDITION monitoring is usually not required because the absence or degradation of the ventilatory support is not likely to cause injury to the PATIENT (i.e. VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT has no ESSENTIAL PERFORMANCE).

201.3.203

VENTILATORY INSUFFICIENCY

RESPIRATORY INSUFFICIENCY

degradation in respiratory function severe enough to prohibit certain activities that the PATIENT might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal

Note 1 to entry: PATIENTS with VENTILATORY INSUFFICIENCY exhibit an illness acuity, fragility or instability level up to and including a moderate to severe degradation in respiratory function. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange can range from minimal to moderate dependence. Without such support, the most fragile of these PATIENTS would likely be prohibited from certain activities that they might normally pursue and this would likely interfere with their daily living. The most fragile of these PATIENTS would likely experience injury with the loss of this artificial ventilation.

EXAMPLES PATIENTS with moderate to severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy.

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for RESPIRATORY INSUFFICIENCY is suitable for use where some PHYSIOLOGICAL ALARM CONDITION monitoring is required to prevent the absence or degradation of the ventilatory support, which in turn could cause the compromise of the health of the PATIENT.

[SOURCE: ISO 80601-2-80:2018[1], definition 201.3.204]

201.3.204
VENTILATOR
VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT
ME EQUIPMENT intended to augment or provide ventilation of the lungs of a PATIENT who is dependent on this ventilation in the HOME HEALTHCARE ENVIRONMENT

Note 1 to entry: For the purposes of this part of ISO 80601, dependent means needed for the majority of the day (e.g. an average need of more than 16 h of ventilation per day).

Note 2 to entry: A VENTILATOR FOR VENTILATOR-DEPENDENT PATIENT is typically used without continuous HEALTHCARE PROFESSIONAL supervision.

Note 3 to entry: As this VENTILATOR is intended to be applied to PATIENTS who are VENTILATOR-DEPENDENT, the VENTILATOR is considered to be a life-sustaining ME EQUIPMENT or ME SYSTEM.

[SOURCE: ISO 80601-2-72:2015, definition 201.3.217, modified, replaced 'supporting' with 'sustaining'.]

201.3.205
VENTILATORY SUPPORT EQUIPMENT
ME EQUIPMENT, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a PATIENT who is not VENTILATOR-DEPENDENT

Note 1 to entry: VENTILATORY SUPPORT EQUIPMENT is a type of VENTILATOR, but is not a VENTILATOR for VENTILATOR-DEPENDENT PATIENT.

Note 2 to entry: A PATIENT suitable for VENTILATORY SUPPORT EQUIPMENT requires a narrow spectrum of ventilation modalities and monitoring for appropriate management.

[SOURCE: ISO 80601-2-80:2018[1], definition 201.3.205]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012, Clause 4, applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

a) For the purposes of this document, VENTILATORY SUPPORT EQUIPMENT FOR VENTILATORY IMPAIRMENT is considered not to have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this document refers to ESSENTIAL PERFORMANCE as acceptance criteria, the continuous pressure shall be evaluated.

b) The method of subclause 202.8.1.101 may be used to evaluate continuous pressure as an acceptance criterion following specific tests required by this document.

NOTE A continuous pressure mode is often referred to as a continuous positive airway pressure (CPAP) mode.

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Amendment (add at end of 4.6 prior to the compliance check):

aa) The VBS or its parts or ACCESSORIES that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS according to this subclause.

Additional subclauses:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) If the VENTILATORY SUPPORT EQUIPMENT is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then it:

   1) shall operate and meet the requirements of this part of ISO 80601 throughout its RATED range of input pressure; and

   2) shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

   NOTE 1 Internal pressure regulators can be necessary to accommodate the SINGLE FAULT CONDITION of maximum input pressure, as well as the RATED range of input pressure.

   NOTE 2 Under the SINGLE FAULT CONDITION of overpressure, it is desirable for gas to continue to flow to the VBS. Under this condition, the flowrate from the VENTILATORY SUPPORT EQUIPMENT is likely to be outside of its specification.

b) If the VENTILATORY SUPPORT EQUIPMENT has a maximum RATED input pressure in excess of 600 kPa, the VENTILATORY SUPPORT EQUIPMENT shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings, by functional testing in SINGLE FAULT CONDITION and inspection of the RISK MANAGEMENT FILE.

201.4.11.101.2 Compatibility requirement

If the VENTILATORY SUPPORT EQUIPMENT is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then

a) the RATED range of input pressure shall cover the range specified in ISO 7396-1, and

b) under NORMAL CONDITION,

   1) the maximum 10 s average input flowrate required by the VENTILATORY SUPPORT EQUIPMENT for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port, and

2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s, or

3) the ACCOMPANYING DOCUMENTS shall disclose the following:

   i) the maximum 10 s average input flowrate required by the VENTILATORY SUPPORT EQUIPMENT for each gas at a pressure of 280 kPa, measured at the gas input port;

   ii) the maximum transient input flowrate averaged for 3 s required by the VENTILATORY SUPPORT EQUIPMENT for each gas at a pressure of 280 kPa, measured at the gas input port; and

   iii) a warning to the effect that this ventilator is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of adjacent equipment.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings and by inspection of the ACCOMPANYING DOCUMENTS.

EXAMPLE The highest driving gas consumption, the highest FRESH GAS delivery, and, if provided, the highest RATED gas consumption at any gas power supply output can be the most adverse conditions.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 5, applies, except as follows:

Additional subclauses:

201.5.101 * Additional requirements for the general requirements for testing of ME EQUIPMENT

201.5.101.1 VENTILATORY SUPPORT EQUIPMENT test conditions

a) For testing, the VENTILATORY SUPPORT EQUIPMENT:

   1) shall be connected to gas supplies as specified for NORMAL USE;

   2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated;

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

NOTE This subclause is only applicable to VENTILATORY SUPPORT EQUIPMENT intended to be connected to a gas supply in NORMAL USE (e.g. MEDICAL GAS PIPELINE SYSTEM or medical gas cylinder).

201.5.101.2 * Gas flowrate and leakage specifications

In this document, requirements for the flowrate, volume and leakage are expressed at STANDARD TEMPERATURE AND PRESSURE, DRY (STPD), except for those associated with the VBS, which are expressed at BODY TEMPERATURE AND PRESSURE, SATURATED (BTPS).

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 * VENTILATORY SUPPORT EQUIPMENT testing errors

a) For the purposes of this document, declared tolerances shall include the measurement uncertainty.

b) The MANUFACTURER shall disclose the measurement uncertainty of each disclosed tolerance in the technical description.

Check compliance by inspection of the instructions for use and the technical description.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 6, applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+AMD1:2012, Clause 7, applies, except as follows:

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

a) ACCESSORIES supplied separately shall

   1) fulfil the requirements of 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101, and

   2) be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, if applicable.

b) If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

NOTE The MANUFACTURER of the ACCESSORY can be the VENTILATORY SUPPORT EQUIPMENT MANUFACTURER or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure compliance with this requirement. Additional requirements are found in 201.102.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.13.101 Additional requirements for physiological effects

a) Any natural rubber latex-containing components or ACCESSORIES in the GAS PATHWAYS shall be marked as containing latex.

b) Such marking shall be CLEARLY LEGIBLE.

c) Symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4) may be used.

d) The instructions for use shall disclose any natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

a) The marking on packages shall be CLEARLY LEGIBLE and shall include:

   1) a description of the contents;

   2) an identification reference to the batch, type or serial number or symbols 5.1.5, 5.1.6 or 5.1.7 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 1, symbol 2 or symbol 3);

   3) for packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4);

b) For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE.

Check compliance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

a) The marking of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

   1) any particular warnings or precautions relevant to the immediate operation of the VENTILATORY SUPPORT EQUIPMENT.

b) If applicable, marking of OPERATOR-detachable ME EQUIPMENT parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

   1) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;

   2) a warning not to obstruct the GAS INTAKE PORT.

   EXAMPLE WARNING: Gas Intake – Do not obstruct.

Check compliance by inspection.

201.7.4.2 Control devices

IEC 60601-1:2005+AMD1:2012, 7.4.2, applies, except as follows:

Amendment (add after the second dash):

aa) The marking of the trigger sensitivity control, if provided, shall be such that the minimum (least PATIENT effort) and the maximum (greatest PATIENT effort) settings are self-evident to the OPERATOR.

bb) The marking, if numeric, shall:

   1) use the lowest number to represent the setting for the least PATIENT effort; and

   2) not only be numeric.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3, applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

aa) All gas volume, flowrate and leakage specifications: 1) shall be expressed at STPD (STANDARD TEMPERATURE AND PRESSURE, DRY); 2) except those associated with the VBS which shall be expressed at BTPS (BODY TEMPERATURE AND PRESSURE, SATURATED). bb) The unit of AIRWAY PRESSURE measurement shall be capable of being configured to be expressed in hPa.

201.7.9.1 Additional general requirements

IEC 60601-1:2005+AMD1:2012, 7.9.1, applies, except as follows:

Amendment (replace the first dash with):

— name or trade name and address of the MANUFACTURER; and

— where the manufacturer does not have an address within the locale, an authorized representative within the locale to which the responsible organization can refer.

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012, 7.9.2, applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

a) Separate instructions for use shall be provided for:

   1) the LAY OPERATOR; and

   2) the HEALTHCARE PROFESSIONAL OPERATOR.

b) The MANUFACTURER may choose in which instructions for use to place the information required by this document unless otherwise indicated in this document based on RISK MANAGEMENT and USABILITY considerations.

c) The HEALTHCARE PROFESSIONAL OPERATOR instructions for use shall include the information contained in the LAY OPERATOR instructions for use.

Check compliance by inspection of the instructions for use, the RISK MANAGEMENT FILE and the USABILITY ENGINEERING FILE.

201.7.9.2.1.102 Additional general requirements

The instructions for use shall:

a) if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES were reused;

b) if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES are intended for single use, information regarding

   1) the intended duration of use; and

   2) the consequences for the PATIENT if use is beyond the specified duration of use.

Check compliance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include:

a) a warning statement to the effect that “WARNING: Do not cover the ventilator or place in a position that affects proper operation”, including applicable examples.

   EXAMPLE 1 WARNING: Do not position next to a curtain that blocks the flow of cooling air, thereby causing the ventilator to overheat.

   EXAMPLE 2 WARNING: Do not block the gas intake port or emergency intake port, thereby interfering with patient ventilation.

   EXAMPLE 3 WARNING: When using the ventilator in a carrying case, only use a carrying case that is listed in the instructions for use, to prevent the ventilator from overheating or interfering with patient ventilation.

b) * a warning statement to the effect that “WARNING: Do not add any attachments or accessories to the ventilator that are not intended for use in combination with the ventilator, as stated in the instructions for use of the ventilator or accessory as the ventilator might not function correctly leading to the risk of degradation or loss of ventilatory support.”

c) * if the instructions for use include a VBS configuration with a BSF exposed to the humidity from nebulisation or humidification, a warning statement to the effect that "WARNING: When using nebulisation or humidification, the breathing system filter will require more frequent replacement to prevent increased resistance or blockage."

d) a warning statement to the effect that "WARNING: This ventilator is not suitable for a ventilator-dependent patient."

Check compliance by inspection of the instructions for use.

201.7.9.2.8.101 * Additional requirements for start-up PROCEDURE

NOTE 1 For the purposes of this document, a start-up PROCEDURE is a pre-use functional test that is used for the initial setup for a PATIENT to determine whether the VENTILATORY SUPPORT EQUIPMENT is ready for use.

a) The instructions for use for the LAY OPERATOR shall disclose a method by which:

   1) the assembled breathing tubes and related ACCESSORIES; and

   2) if provided, the switchover to and operation from the INTERNAL ELECTRICAL POWER SOURCE;

   can be functionally tested to determine if they are operating correctly.

   NOTE 2 Additional requirements are also found in 201.15.102.

b) The instructions for use for the HEALTHCARE PROFESSIONAL OPERATOR shall disclose a test method:

   1) by which all functions and settings necessary for NORMAL USE can be functionally tested to determine if they are operating correctly; and

   2) which can determine whether or not the assembled breathing tubes and related ACCESSORIES are suitable for use.

      i) Portions of this test method may be performed automatically by the VENTILATORY SUPPORT EQUIPMENT or may require OPERATOR action.

      ii) This test method should be as automated as practicable.

Check compliance by inspection of the instructions for use and functional testing.

201.7.9.2.9.101 * Additional requirements for operating instructions

201.7.9.2.9.101.1 LAY OPERATOR operating instructions

a) The instructions for use intended for the LAY OPERATOR shall include

   1) the conditions under which the VENTILATORY SUPPORT EQUIPMENT maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use;

      EXAMPLE 1 Acceptable range of water level in a HUMIDIFIER.

      EXAMPLE 2 Interval of calibration of a flow sensor.

   2) a statement to the effect that "Do not use the ventilator at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range]. Using the ventilator outside of this temperature range or above this altitude can compromise the ventilator performance";

3) a statement to the effect that "To reduce the likelihood of disconnection and to prevent adverse ventilator performance use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories";

4) if applicable, a statement to the effect that "The ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser."

b) The instructions for use intended for the LAY OPERATOR shall include

1) a description of a means to determine the operation time of the INTERNAL ELECTRICAL POWER SOURCE, if provided,

2) a description of how to connect and test the connection of a DISTRIBUTED ALARM SYSTEM, if provided.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101.2 HEALTHCARE PROFESSIONAL OPERATOR operating instructions

a) The instructions for use intended for the HEALTHCARE PROFESSIONAL OPERATOR shall include a detailed description of the function of all ventilation modes provided by the VENTILATORY SUPPORT EQUIPMENT including, but not limited to, the following items:

1) the working principle of each of the VENTILATORY SUPPORT EQUIPMENT'S ventilation modes, including waveforms;

2) the methods for controlling the cycling;

3) the parameter settings;

4) the range of parameter settings; and

5) any limitation of parameter settings.

b) The instructions for use intended for the HEALTHCARE PROFESSIONAL OPERATOR shall include

1) the RATED range of the following characteristics of the assembled OPERATOR-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained:

i) inspiratory GAS PATHWAY resistance;

ii) expiratory GAS PATHWAY resistance; and

iii) compliance.

2) the intended range of DELIVERED VOLUME.

c) These specifications may be presented in ranges.

d) The accuracies of set and monitored volumes may be presented as a function of these characteristics.

NOTE Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate or the maximum pressure).

e) If applicable, instructions for use intended for the HEALTHCARE PROFESSIONAL OPERATOR shall disclose

1) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER.

EXAMPLES Dead space and resistance.

Check compliance by inspection of the instructions for use.

201.7.9.2.12 CLEANING, DISINFECTION, and STERILIZATION

IEC 60601-1:2005+AMD1:2012, 7.9.2.12, applies, except as follows:

Amendment: (add after NORMAL USE)

and SINGLE FAULT CONDITION

Amendment: (add after bulleted list)

aa) The instructions for use shall identify any portions of the GAS PATHWAYS through the VENTILATORY SUPPORT EQUIPMENT that can become contaminated with body fluids or by microbial material conveyed by the expired breathing gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The instructions for use shall disclose

a) a description of periodic safety inspections that should be performed by the OPERATOR,

b) if provided, the care and maintenance PROCEDURES for the INTERNAL ELECTRICAL POWER SOURCE, including instructions for recharging and, if applicable, replacement.

Check compliance by inspection of the instructions for use.

201.7.9.2.14.101 * Additional requirements for ACCESSORIES, supplementary equipment, used material

If applicable, the instructions for use shall disclose

a) any restrictions on the positioning of components within the VENTILATOR BREATHING SYSTEM,

EXAMPLE Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

b) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the VENTILATORY SUPPORT EQUIPMENT.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose:

a) a summary description of the filtering or smoothing techniques for measured or computed variables that are displayed or used for control necessary for the OPERATOR to form a mental model of the operation of the VENTILATORY SUPPORT EQUIPMENT;

b) the interdependence of control functions;

c) a pneumatic diagram of the VENTILATORY SUPPORT EQUIPMENT, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use;

d) a summary description of the means of initiating and terminating the inspiratory phase while the VENTILATORY SUPPORT EQUIPMENT is operating in each of its ventilatory modes;

e) a statement to the effect that prior to use the responsible organization needs to ensure the compatibility of the ventilator and all of the parts and accessories with which the ventilator is intended to be used.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 8, applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 9, applies, except as follows:

Additional subclause:

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

a) TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT shall include a means by which the VENTILATORY SUPPORT EQUIPMENT can be secured without the use of a TOOL to prevent unwanted movement during transport while in use.

b) The means shall secure the VENTILATORY SUPPORT EQUIPMENT to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 5 s each.

EXAMPLES Means to restrain physically the VENTILATORY SUPPORT EQUIPMENT during transport in a personal vehicle, in an ambulance or on a wheelchair.

Check compliance by functional testing.

201.9.4.4 Grips and other handling devices

Amendment (replace list item b) with):

b) TRANSIT-OPERABLE VENTILATORY SUPPORT EQUIPMENT shall be designed either:

1) with a handle that does not require more than one hand; or

2) to be used with a carrying case or in-use bag.

Check compliance by carrying with one hand.

Additional subclauses:

201.9.6.2.1.101 Additional requirements for audible acoustic energy

a) The A-weighted sound pressure level emitted by the VENTILATORY SUPPORT EQUIPMENT shall be measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2 and disclosed in the instructions for use.

b) The A-weighted sound power level shall be calculated according to 8.1 of ISO 3744:2010 and disclosed in the instructions for use.

Check compliance with the following test.

c) Place the VENTILATORY SUPPORT EQUIPMENT on a sound-reflecting plane and attach the least favourable VBS from those indicated in the instructions for use.

NOTE The least favourable VBS configuration can vary by mode, breath type and flow pattern, as applicable.

d) *If a HUMIDIFIER is provided with or specified in the ACCOMPANYING DOCUMENTS of the VENTILATORY SUPPORT EQUIPMENT, include the HUMIDIFIER in the test and fill to the least favourable level.*

e) *Connect the standard resistance, 40 mm length and outlet angle of 45° (as indicated in Figure 201.101) to the PATIENT-CONNECTION PORT.*

f) *Acoustically isolate the BREATHING TUBES and the standard resistance out of the testing area such that the noise of the gas flowing through the BREATHING TUBES and exiting the standard resistance does not interfere with the sound measurement of the VENTILATORY SUPPORT EQUIPMENT.*

g) *Set the VENTILATORY SUPPORT EQUIPMENT to a mode that generates a continuous pressure of 10 hPa (10 cmH_2O) at the PATIENT-CONNECTION PORT.*

h) *Using a microphone of a sound level meter, complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at 10 positions in a hemisphere with a radius from the geometric centre of the VENTILATORY SUPPORT EQUIPMENT as specified in 7.2 of ISO 3744:2010.*

i) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.1 of ISO 3744:2010.*

j) *Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.*

k) *Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.*

l) *Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744:2010. Average the values in accordance with 8.1 of ISO 3744:2010.*

m) *Repeat d) to l) for each HUMIDIFIER provided with or specified in the ACCOMPANYING DOCUMENTS.*

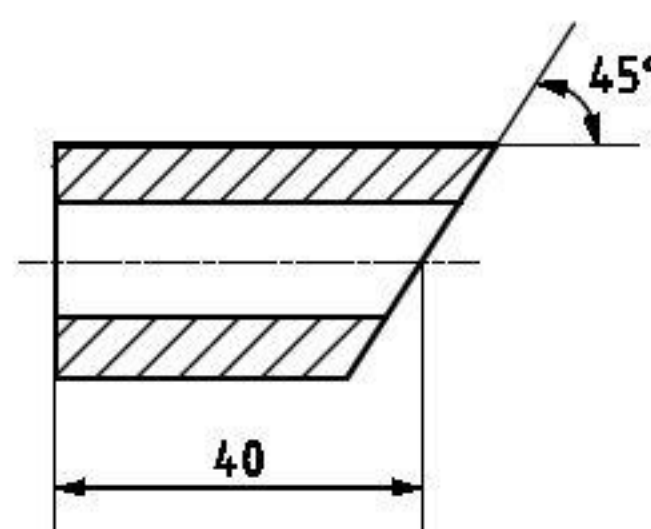
n) *Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.*

NOTE The internal diameter is 4 mm.

Figure 201.101 — Standard resistance

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 10, applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 11, applies, except as follows:

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

Amendment (add between the existing paragraphs):

Over the RATED flowrate range and at the maximum RATED operating temperature, the temperature of the gas delivered by the VENTILATORY SUPPORT EQUIPMENT at the PATIENT-CONNECTION PORT, both with and without a HUMIDIFIER, shall not exceed an energy equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m^3 dry air) when averaged over 120 s.

Table 201.101 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.101 — Examples of permissible combinations of temperature and relative humidity

Temperature °C	Relative humidity %
43	100
44	95
45	90
48	76
50	71

201.11.6.6 * CLEANING and DISINFECTION of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

aa) GAS PATHWAYS through the VENTILATOR and its ACCESSORIES that can become contaminated with body fluids or by microbial material conveyed by the expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow:

1) for CLEANING and DISINFECTION; or

2) CLEANING and STERILIZATION.

NOTE Additional requirements are found in IEC 60601-1:2005, 11.6.7+AMD1:2012 and IEC 60601-1-11:2015, Clause 8.

bb) Dismantling or parts replacement may be performed.

Amendment (add additional requirement and replace the compliance test):

cc) VENTILATOR ENCLOSURES shall be designed to allow for surface CLEANING and DISINFECTION to reduce to acceptable levels the RISK of infection of OPERATORS, bystanders, or the PATIENT.

dd) Instructions for PROCESSING the VENTILATOR and its ACCESSORIES shall:

1) comply with ISO 17664:2017; and

2) be disclosed in the instructions for use.

NOTE 1 ISO 14159[9] provides guidance for the design of ENCLOSURES.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this document could be affected by the CLEANING or the disinfecting of the VENTILATOR or its parts or ACCESSORIES, clean and disinfect them 10 times in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these PROCEDURES, ensure that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Confirm that the MANUFACTURER has evaluated the effects of multiple processing cycles and the effectiveness of those cycles.

NOTE 2 Additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 STERILIZATION of ME EQUIPMENT or ME SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are found in IEC 60601-1:2005+AMD1:2012, 11.6.6 and IEC 60601-1-11:2015, Clause 8.

201.11.7 BIOCOMPATIBLITY of ME EQUIPMENT and ME SYSTEMS

Amendment (add after existing text prior to the compliance statement):

aa) The MANUFACTURERS of the VENTILATORY SUPPORT EQUIPMENT, the VBS, their parts and ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the BIOCOMPATIBILITY and potential contamination of the gas stream arising from the GAS PATHWAYS.

bb) The GAS PATHWAYS shall be evaluated for BIOCOMPATIBILITY according to ISO 18562-1:2017.

cc) Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

dd) The VENTILATORY SUPPORT EQUIPMENT, the VBS, their parts or ACCESSORIES that contain phthalates or other substances, in a concentration that is above 0,1 % weight by weight, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, shall be marked as containing such substances:

1) on the device itself; or

2) on the packaging.

ee) The symbols of

1) EN 15986:2011 (Table 201.D.2.101, symbol 5) may be used for phthalates;

2) ISO 7000-2725 (Table 201.D.2.101, symbol 6) may be used for other substances.

ff) If the INTENDED USE of the VENTILATORY SUPPORT EQUIPMENT, the VBS, their parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these shall be included in the RISK MANAGEMENT FILE.

gg) The instructions for use shall contain information:

1) on RESIDUAL RISKS for these PATIENT groups; and

2) if applicable, on appropriate precautionary measures.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

201.11.8 Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

Additional subclause:

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT ALARM CONDITION

201.11.8.101.1 ALARM CONDITIONS

a) VENTILATORY SUPPORT EQUIPMENT may be equipped with an INTERNAL ELECTRICAL POWER SOURCE.

b) If equipped, the VENTILATORY SUPPORT EQUIPMENT shall

1) be equipped with an automatic switchover to the INTERNAL ELECTRICAL POWER SOURCE when the SUPPLY MAINS falls outside the values necessary to maintain normal operation;

2) provide a means for determining the state of this INTERNAL ELECTRICAL POWER SOURCE;

3) provide a means to indicate that the VENTILATORY SUPPORT EQUIPMENT is powered from the INTERNAL ELECTRICAL POWER SOURCE.

c) The INSTRUCTIONS for use shall disclose

1) the operational time of the VENTILATORY SUPPORT EQUIPMENT when powered from each power source under the following conditions a fully charged power source and the conditions of Table 201.102;

2) the behaviour of the VENTILATORY SUPPORT EQUIPMENT after a switch-over to the INTERNAL ELECTRICAL POWER SOURCE;

3) the behaviour of the VENTILATORY SUPPORT EQUIPMENT while the recharging of the INTERNAL ELECTRICAL POWER SOURCE.

Check compliance by functional testing and inspection of the instructions for use.

201.11.8.101.2 Alternative power supply/SUPPLY MAINS

a) If the VENTILATORY SUPPORT EQUIPMENT is equipped with a means of connection to an alternative SUPPLY MAINS, the instructions for use shall include

1) a description of the means of connection;

2) the RATED voltage range;

3) the NOMINAL voltage range;

4) the maximum current required.

b) If the VENTILATORY SUPPORT EQUIPMENT is TRANSIT-OPERABLE, a means of connection to an automotive vehicle power source should be provided.

EXAMPLES A 12 V d.c., 100 W connector or other MAINS CONNECTOR.

Check compliance by inspection and inspection of the instructions for use.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+AMD1:2012, Clause 12, applies, except as follows:

Additional subclauses:

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The VENTILATORY SUPPORT EQUIPMENT may provide means to reduce the visibility of its controls and indicators either automatically or by the OPERATOR action.

bb) If a means to reduce the visibility is provided, the VENTILATORY SUPPORT EQUIPMENT shall automatically resume normal visibility during an ALARM CONDITION.

cc) The controls and indicators of VENTILATORY SUPPORT EQUIPMENT shall be CLEARLY LEGIBLE under the conditions specified in IEC 60601-1:2005+AMD1:2012, 7.1.2.

Check compliance by functional testing and application of the tests of and IEC 60601-1:2005+AMD1:2012, 7.1.2.

201.12.1.101 Volume-controlled breath type

a) If a volume-controlled breath type is provided, then with a volume-controlled breath type selected and the VENTILATORY SUPPORT EQUIPMENT operating in NORMAL CONDITION, the accuracy, as the maximum bias error and maximum linearity error and as determined for the test settings and conditions specified in this document, shall be disclosed in the instructions for use.

EXAMPLE ±[5 + (10 % of the set volume)] ml.

b) This disclosure shall include at least:

1) the maximum error of the DELIVERED VOLUME in relation to the set value; and

2) the maximum error of the PEEP in relation to the set value.

c) All of the errors may be separately reported for the following ranges of intended DELIVERED VOLUME:

1) $V_{del} \geq 300$ ml; and

2) 300 ml $\geq V_{del} \geq 50$ ml.

d) The accuracy of the performance of the VENTILATORY SUPPORT EQUIPMENT shall either be:

1) determined for each VBS configuration indicated in the instructions for use; or

2) determined for the worst-case VBS configurations indicated in the instructions for use.

NOTE 1 The worst-case VBS configuration can be different for each error or NOMINAL DELIVERED VOLUME.

e) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the following tests for DELIVERED VOLUME and end-expiratory pressure errors:

f) Set up the VENTILATORY SUPPORT EQUIPMENT as shown in Figure 201.102.

g) If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a HUMIDIFIER is used, fill the HUMIDIFIER to the maximum water level prior to determining the VBS compliance.

h) Utilize the test parameters and settings of the first applicable row (selected by intended DELIVERED VOLUME) of Table 201.102. Wait for steady-state conditions to be achieved.

i) Determine the DELIVERED VOLUME, for example by integration of the flow signal provided by a calibrated flow sensor located at the PATIENT-CONNECTION PORT or by the product of the test lung compliance and the measured change of lung pressure compensated, if necessary, for temperature effects due to fast compression of the gas, if necessary.

NOTE 2 Additional information on the construction of an isothermal test lung is found in reference[10].

j) *Compare the result with the volume setting for the test. Confirm that the accuracy is within the tolerance indicated in the instructions for use.*

k) *Determine the PEEP as the average of the AIRWAY PRESSURE measurements over the last 50 ms of the expiratory phase.*

l) *Compare the result with the PEEP setting for the test. Confirm that the resulting difference is within the tolerance indicated in the instructions for use.*

m) *Repeat h) to l) for 30 consecutive breaths.*

n) *Repeat h) to m) for each applicable row (selected by intended DELIVERED VOLUME) of Table 201.102.*

o) *If a HUMIDIFIER is included in the VBS, repeat the DELIVERED VOLUME tests with the minimum HUMIDIFIER water level without re-determining the VBS compliance.*

p) *Unless it can be demonstrated that the worst-case flow pattern (e.g. constant flow, decelerating flow) has been selected for the tests, repeat g) to o) for each flow pattern available on the VENTILATORY SUPPORT EQUIPMENT.*

q) *If the VENTILATORY SUPPORT EQUIPMENT permits operation without compliance correction, repeat g) to p) without compliance correction.*

Key

1 VENTILATORY SUPPORT EQUIPMENT under test (single or dual limb)
2 pressure sensor
3 flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms (applies for volume-controlled breath type only)
4 artificial leakage (applies for pressure-controlled breath type only), see Table 201.103, note b
5 data acquisition system, with minimum sample rate of 200 samples/s
6 temperature sensor
7 resistance in series with the test lung (R_{lung})
8 pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
9 compliance of the test lung (C_{lung})
10 test lung

Figure 201.102 —Typical test setup for volume- and pressure-control breath type accuracy

Table 201.102 — Volume-controlled breath TYPE TEST settings

Test number	Test lung parameters		Ventilatory support equipment settings			
	Compliance (ml(hPa)$^{-1}$) ±10 %	Linear[11][12][13] resistance (hPa(l/s)$^{-1}$) ±10 %	Volume (ml)	Ventilatory frequency[a] (breaths/min)	Inspiratory time (s)	Peep (hPa)
1	50	5	500	20	1	5
2	50	20	500	12	1	10
3	20	5	500	20	1	5
4	20	20	500	20	1	10
5	20	20	300	20	1	5
6	20	50	300	12	1	10
7	10	50	300	20	1	10
8	10	20	200	20	1	5

[a] In the case that end-expiratory flow does not reach zero, reduce the ventilatory frequency until it does for at least 50 ms.

201.12.1.102 Pressure-controlled breath type

a) If a pressure-controlled breath type is provided, then with a pressure-controlled breath type selected and the VENTILATORY SUPPORT EQUIPMENT operating in NORMAL CONDITION, the accuracy as determined for the test settings and conditions specified in this document shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ± [3,0 + (5 % of the set pressure)] hPa.

b) This disclosure shall include at least:

1) the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the inspiratory phase in relation to the set value;

2) the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the inspiratory phase in relation to the set value under leak condition;

3) the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the expiratory phase in relation to the set value;

4) the maximum error of the AIRWAY PRESSURE (P_{aw}) at the end of the expiratory phase in relation to the set value under leak condition.

c) All of the errors may be separately reported for the following ranges of intended DELIVERED VOLUME:

1) $V_{del} \geq 300$ ml;

2) 300 ml $\geq V_{del} \geq$ 50 ml.

d) The accuracy of the performance of the VENTILATORY SUPPORT EQUIPMENT shall either be:

1) determined for each VBS configuration indicated in the instructions for use; or

2) determined for the worst-case VBS configuration indicated in the instructions for use.

NOTE 1 The worst-case VBS configuration can be different for each error or each NOMINAL DELIVERED VOLUME range.

e) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the following tests for end-inspiratory and end-expiratory pressure errors:

f) Set up the VENTILATORY SUPPORT EQUIPMENT as shown in Figure 201.102.

g) If applicable, determine or input the VBS compliance required for compliance correction as indicated in the instructions for use and activate this correction. If a HUMIDIFIER is used, fill the HUMIDIFIER to the maximum water level prior to determining the VBS compliance.

h) Utilize the test parameters and settings of the first applicable row (selected by typical intended DELIVERED VOLUME) of Table 201.103. Wait until steady-state conditions are achieved.

Table 201.103 — Pressure-controlled breath TYPE TEST settings

Test number	Intended DELIVERED VOLUME[a] (ml)	Test lung parameters			VENTILATORY SUPPORT EQUIPMENT settings			
		Compliance (ml(hPa)$^{-1}$) ±10 %	Linear[11][12][13] Resistance (hPa(l/s)$^{-1}$) ±10 %	Leakage[b] (ml/min) ±10 %	Ventilatory frequency[c] (breaths/min)	Inspiratory time[d] (s)	Pressure[e] (hPa)	PEEP (hPa)
1	500	50	5	0	20	1	10	5
2	500	50	20	0	12	1	15	10
3	500	20	5	0	20	1	25	5
4	500	20	20	0	20	1	25	10
5	500	50	5	5 000	20	1	25	5
6	500	50	20	10 000	12	1	25	10
7	300	20	20	0	20	1	15	5
8	300	20	50	0	12	1	25	10
9	300	10	50	0	20	1	30	5
10	300	20	20	3 000	20	1	25	5
11	300	20	50	6 000	12	1	25	10
12	200	10	20	0	20	1	25	10

[a] The volume in this column is intended to be used for the selection of the test conditions and parameters based on the intended DELIVERED VOLUME of the VENTILATORY SUPPORT EQUIPMENT.

[b] For the purpose of this test, the VBS under test is set up with the artificial leakage (item 4 in Figure 201.102) at a constant pressure of 20 hPa.

[c] In the case that end-expiratory flow does not reach zero, reduce the ventilatory frequency until it does for at least 50 ms.

[d] The rise time of the VENTILATORY SUPPORT EQUIPMENT should be set to a value that ensures that the set pressure can be reached within the INSPIRATORY TIME.

[e] For the purposes of this test, the set pressure is relative to set AIRWAY PRESSURE at the end of the expiratory phase.

i) Determine the AIRWAY PRESSURE at the end of the inspiratory phase as the average over the preceding 50 ms.

j) Compare the result with the pressure setting for the test. Confirm that the resulting difference is within the tolerance indicated in the instructions for use.

k) Determine the DELIVERED VOLUME, for example by integration of the flow signal provided by a calibrated flow sensor located at the PATIENT-CONNECTION PORT or for VENTILATORY SUPPORT EQUIPMENT that indicates a leakage-compensated DELIVERED VOLUME by the product of the test lung compliance and the measured change of lung pressure, if necessary, compensated for temperature effects due to fast compression of the gas.

NOTE 2 Additional information on the construction of an isothermal test lung is found in reference[10].

l) Determine the AIRWAY PRESSURE at the end of the expiratory phase as the average of the AIRWAY PRESSURE measurements over the last 50 ms of the expiratory phase.

m) Compare the result with the setting for the test. Confirm that the resulting difference is within the tolerance indicated in the instructions for use.

n) Repeat g) to m) for 30 consecutive breaths.

o) Repeat g) to n) for each applicable row (selected by intended DELIVERED VOLUME) of Table 201.103.

p) If a HUMIDIFIER is included in the VBS, repeat the AIRWAY PRESSURE tests with the minimum HUMIDIFIER water level without re-determining the VBS compliance.

q) If the VENTILATORY SUPPORT EQUIPMENT permits operation without compliance correction, repeat g) to p) without compliance correction.

r) Compare each result to the tolerance indicated in the instructions for use.

201.12.1.103 Other breath types

a) If other breath types are provided, then with each other breath type selected and the VENTILATORY SUPPORT EQUIPMENT operating in NORMAL CONDITION, the performance and their pass-fail criteria, as determined by the MANUFACTURER, shall be disclosed in the instructions for use.

b) All of the pass-fail criteria may be separately reported for the following ranges of intended DELIVERED VOLUME:

1) $V_{del} \geq 300$ ml; and

2) 300 ml $\geq V_{del} \geq 50$ ml.

c) The pass-fail criteria of the performance of the VENTILATORY SUPPORT EQUIPMENT shall either be:

1) determined for each VBS configuration indicated in the instructions for use; or

2) determined for the worst-case VBS configuration indicated in the instructions for use.

NOTE 1 The worst-case VBS configuration can be different for each error or each NOMINAL DELIVERED VOLUME range.

d) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

e) The technical description shall disclose a summary of the test method and the details necessary to reproduce the test results used to test each other breath type.

Check compliance by inspection of the of the ACCOMPANYING DOCUMENTS, inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and with the tests described in the technical description.

201.12.2.101 USABILITY of ME EQUIPMENT

a) Any pressure setting change and its relation to any other pressure settings shall be displayed while the setting is performed.

b) Any setting that affects the I:E ratio or INSPIRATORY TIME shall be displayed with the I:E ratio and INSPIRATORY TIME while the setting is performed.

c) The VENTILATORY SUPPORT EQUIPMENT shall provide the RESPONSIBLE ORGANIZATION with a means to allow the HEALTHCARE PROFESSIONAL OPERATOR to have direct access to the ventilation settings.

EXAMPLES Settings needing protection include ventilatory frequency, I:E ratio, INSPIRATORY TIME, adjustable pressure limitation, high inspiratory pressure ALARM LIMIT, and mode breath type.

Check compliance by functional testing.

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Measurement of AIRWAY PRESSURE

201.12.4.101.1 General

a) The VENTILATORY SUPPORT EQUIPMENT shall be equipped with MONITORING EQUIPMENT to indicate the AIRWAY PRESSURE.

b) The site of actual measurement may be anywhere in the VENTILATOR BREATHING SYSTEM, but the indicated value shall be referenced to the PATIENT-CONNECTION PORT.

c) Under steady-state conditions, the indicated AIRWAY PRESSURE shall be accurate to within ±(2 + 4 % of the actual reading) hPa (cmH_2O).

Check compliance by functional testing.

201.12.4.101.2 Low airway pressure alarm condition

If the AIRWAY PRESSURE MONITORING EQUIPMENT is equipped with an ALARM SYSTEM:

a) the AIRWAY PRESSURE MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate when the low-AIRWAY PRESSURE ALARM LIMIT is reached;

b) the low-AIRWAY PRESSURE ALARM CONDITION

1) shall be at least a MEDIUM PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the

i) low-AIRWAY PRESSURE ALARM CONDITION is suppressed, or

ii) its priority is changed, or

3) may start at LOW PRIORITY, and

4) if this state continues, escalates to a MEDIUM PRIORITY ALARM CONDITION;

c) the low-AIRWAY PRESSURE ALARM SIGNAL may be inactivated with ALARM OFF;

d) ALARM OFF may be activated by the VENTILATORY SUPPORT EQUIPMENT;

e) the low-airway pressure ALARM LIMIT may be

1) pre-adjusted;

2) RESPONSIBLE ORGANIZATION-adjustable;

3) OPERATOR-adjustable;

4) VENTILATORY SUPPORT EQUIPMENT-adjustable; or

5) a combination of OPERATOR-adjustable and VENTILATORY SUPPORT EQUIPMENT-adjustable;

f) If the AIRWAY PRESSURE ALARM LIMIT is adjustable by the VENTILATORY SUPPORT EQUIPMENT, a summary description of the algorithm that determines the ALARM LIMIT value shall be disclosed in the instructions for use.

NOTE Depending on the type of ventilation mode being utilized, there can be more than one active ALARM LIMIT.

Check compliance by functional testing.

201.12.4.102 Measurement of expired volume

If VENTILATORY SUPPORT EQUIPMENT is equipped with MONITORING EQUIPMENT for indicating the volume expired through the PATIENT-CONNECTION PORT, the accuracy shall be disclosed in the instructions for use.

201.12.4.103 * MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

a) A PROTECTION DEVICE shall be provided to prevent the AIRWAY PRESSURE from exceeding the MAXIMUM LIMITED PRESSURE under both NORMAL CONDITION and SINGLE FAULT CONDITION.

b) The MAXIMUM LIMITED PRESSURE shall not exceed 60 hPa (60 cmH_2O).

Check compliance by functional testing.

201.12.4.104 Hypoventilation ALARM CONDITION

a) The VENTILATORY SUPPORT EQUIPMENT may be equipped with MONITORING EQUIPMENT with an ALARM SYSTEM that detects an ALARM CONDITION to indicate hypoventilation.

b) If equipped, the ALARM SYSTEM shall be equipped with an ALARM OFF for the ALARM CONDITION that indicates hypoventilation.

NOTE The hypoventilation ALARM CONDITION can be determined, *inter alia*, by the measurement of the variations of AIRWAY PRESSURE, or expired volume, but possibly needs additional detection means. The hypoventilation ALARM CONDITION can also be determined by an INTELLIGENT ALARM SYSTEM utilizing one or more variables.

Check compliance by functional testing.

201.12.4.105 * CO_2 REBREATHING

a) VENTILATORY SUPPORT EQUIPMENT shall be designed so that REBREATHING of carbon dioxide is minimised to an acceptable level as specified by 5.3 of ISO 17510:2015.

NOTE The design of the VENTILATORY SUPPORT EQUIPMENT can be such that this requirement is satisfied without a designated MASK or ACCESSORY.

b) The non-rebreathing performance of the VENTILATORY SUPPORT EQUIPMENT shall either be:

1) determined for each VBS configuration indicated in the instructions for use; or

2) determined for the worst-case VBS configurations indicated in the instructions for use.

NOTE 1 The worst-case VBS configuration can be different for each error or NOMINAL DELIVERED VOLUME.

c) If worst-case VBS configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

d) Use of VENTILATORY SUPPORT EQUIPMENT with a designated MASK or ACCESSORY that complies with ISO 17510:2015 may be used to comply with this requirement. In such a case, the ACCOMPANYING DOCUMENTS shall include:

1) a warning to the effect that "Warning: Failure to use a mask or accessory that minimizes REBREATHING of carbon dioxide or permits spontaneous breathing can cause asphyxiation"; and

2) the list of designated MASKS or ACCESSORIES; or

3) alternatively the necessary information to locate such a list.

EXAMPLE The address of the list on a website.

Check compliance by:

e) inspection of the instruction for use; or

f) where the VENTILATORY SUPPORT EQUIPMENT provides the means of compliance, inspection of the RISK MANAGEMENT FILE and application of limits given in 5.3 of ISO 17510:2015 and the tests of Annex F of ISO 17510:2015, using the VENTILATORY SUPPORT EQUIPMENT as the flow source and replacing the breathing tube by the VBS for the test. Where a MASK is not used, the MASK and simulated PATIENT head of Figure F.1 of ISO 17510:2015 are replaced by a direct connection.

201.12.101 Protection against accidental adjustments

a) Means of protection against accidental adjustment of controls that can create a HAZARDOUS SITUATION shall be provided, including at least that setting the MAXIMUM WORKING PRESSURE greater than 40 hPa shall require at least a sequence of two very deliberate actions.

b) These means may be accomplished by:

1) utilizing hardware or software or a combination of both; or

2) two or more dedicated confirmation actions;

c) the USABILITY of these means of protection shall be evaluated in the USABILITY ENGINEERING PROCESS.

NOTE The requirements for the USABILITY ENGINEERING PROCESS are found in IEC 60601-1:2005+AMD1:2012, 12.2 and IEC 60601-1-6:2010+AMD1:2013.

Check compliance by functional testing and inspection of USABILITY ENGINEERING FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 13, applies, except as follows:

Additional subclauses:

201.13.2.101 * Additional specific SINGLE FAULT CONDITIONS

VENTILATORY SUPPORT EQUIPMENT shall be so constructed that the following SINGLE FAULT CONDITIONS do not cause an unacceptable RISK:

a) misconnection of a VBS control connection, monitoring connection or ACCESSORY connection; or

EXAMPLE Misconnection of supplemental oxygen supply.

b) failure to install, removal of or failure of an OPERATOR-detachable BREATHING SYSTEM FILTER.

Check compliance by functional testing and inspection of RISK MANAGEMENT FILE.

201.13.2.102 * Independence of ventilation control function and related RISK CONTROL measures

a) A SINGLE FAULT CONDITION shall not cause the simultaneous failure of:

1) the ventilation-control function; and

2) the corresponding PROTECTION DEVICE.

b) A SINGLE FAULT CONDITION shall not cause failure in such a way that a failure of:

1) the ventilation-control function and the corresponding MONITORING EQUIPMENT is not detected; or

2) the ventilation-control function and the corresponding ALARM SYSTEM is not detected.

Check compliance by inspection and functional testing.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+AMD1:2012, Clause 14, applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 15, applies, except as follows:

201.15.101 Mode of operation

VENTILATORY SUPPORT EQUIPMENT shall be suitable for continuous operation.

Check compliance by inspection.

201.15.102 Pre-use check

a) The VENTILATORY SUPPORT EQUIPMENT shall be provided with means that allow the following to be functionally tested by the LAY OPERATOR to determine if they are operating correctly and ready for use:

1) the assembled breathing tubes and related ACCESSORIES;

2) switchover to and operation from, if provided, the INTERNAL ELECTRICAL POWER SOURCE;

3) all ALARM SIGNALS, including, if provided, the ALARM SIGNALS from a DISTRIBUTED ALARM SYSTEM; and

4) if provided, high leakage (circuit disconnect) ALARM CONDITION.

b) This test method:

1) should be performed automatically by the VENTILATORY SUPPORT EQUIPMENT; but

2) may require OPERATOR action.

EXAMPLE Combination of the power-on self-test routines and OPERATOR actions that functionally check the ALARM SIGNALS.

NOTE Additional requirements are also found in 201.7.9.2.8.101.

c) The MODEL OR TYPE REFERENCE of any required ACCESSORIES or test equipment needed to perform these tests shall be disclosed in the instructions for use for the LAY OPERATOR.

d) The instructions for use for the LAY OPERATOR shall disclose the PROCEDURE by which tests are performed.

Check compliance by inspection of the instructions for use and functional testing.

VENTILATORY SUPPORT EQUIPMENT shall be provided with means that allows the determination of whether or not the VBS is suitable for use.

NOTE Additional requirements are also found in 201.7.9.2.8.101 a).

Check compliance by functional testing.

201.16 ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 16, applies, except as follows:

Additional subclause:

201.16.1.101 Additional general requirements for ME SYSTEMS

ACCESSORIES connected to the VBS shall be considered to:

a) be part of the VENTILATORY SUPPORT EQUIPMENT; or

b) form an ME SYSTEM with the VENTILATORY SUPPORT EQUIPMENT.

Check compliance by application of the relevant tests of this document and IEC 60601-1:2005+AMD1:2012.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 17, applies.

Additional clauses:

201.101 Gas connections

201.101.1 VBS connectors

201.101.1.1 * General

a) A conical VBS connector shall be either a 15 mm or a 22 mm connector complying with ISO 5356-1:2015 or not engage with those connectors.

b) A non-conical connector shall not engage with a conical connector complying with ISO 5356-1:2015 unless it complies with the engagement, disengagement and leakage requirements of that standard.

c) The VBS, its parts or accessories shall not be equipped with connectors that permit a FUNCTIONAL CONNECTION with a connector complying with ISO 80369-7:2016.

Check compliance by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.1.2 Other named ports

201.101.1.2.1 General

OPERATOR-detachable connectors used within the VBS for:

a) control functions,

b) monitoring functions, and

c) other ACCESSORY functions

shall be non-interchangeable.

Check compliance by functional testing.

201.101.1.2.2 PATIENT-CONNECTION PORT

The PATIENT-CONNECTION PORT shall be one of the following:

a) a female 15 mm conical connector complying with ISO 5356-1:2015; or

b) a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2015.

Check compliance by application of the tests of ISO 5356-1:2015.

201.101.1.2.3 * MANUAL VENTILATION PORT

The VENTILATORY SUPPORT EQUIPMENT shall not be equipped with a MANUAL VENTILATION PORT.

Check compliance by inspection.

201.101.1.2.4 ACCESSORY port

If provided, each ACCESSORY port shall:

a) comply with ISO 80369-1:2010;

NOTE 1 It is expected that the RESP-125 connector of ISO 80369-2[14] will meet this criterion.

b) be provided with a means to secure the ACCESSORY in position; and

c) be provided with a means to secure closure after removal of the ACCESSORY.

NOTE 2 This port connects to the GAS PATHWAY and is generally used for measuring pressure, sampling of gases or for introduction of therapeutic aerosols.

Check compliance by inspection and application of the tests of ISO 80369-1:2010.

201.101.1.2.5 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall:

a) not be compatible with connectors specified in ISO 5356-1:2015;

b) be provided with a means to secure the probe in position; and

c) be provided with a means to secure closure after removal of the probe.

Check compliance by inspection and application of the tests of ISO 5356-1:2015.

201.101.1.2.6 Oxygen inlet port

a) An oxygen inlet connector of the VENTILATORY SUPPORT EQUIPMENT, which is OPERATOR-detachable without the use of a TOOL, shall comply with ISO 80369-1:2010.

NOTE It is expected that the RESP-6000 connector of ISO 80369-2 [14] will meet this criterion.

b) VENTILATORY SUPPORT EQUIPMENT with this inlet connector shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with oxygen supply systems up to 600 kPa, in NORMAL CONDITION.

Check compliance by functional testing and application of the tests of ISO 80369-1:2010.

201.101.1.2.7 FLOW-DIRECTION-SENSITIVE COMPONENTS

Any OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENT of the VBS shall be so designed that it cannot be fitted in such a way that it presents an unacceptable RISK to the PATIENT.

Check compliance by inspection of OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENTS and inspection of the RISK MANAGEMENT FILE.

201.102 Requirements for the VBS and ACCESSORIES

201.102.1 * General

All VENTILATOR BREATHING SYSTEMS, their parts and ACCESSORIES shall comply with the requirements of this document, whether they are produced by the MANUFACTURER of the VENTILATORY SUPPORT EQUIPMENT or by another entity (“third-party manufacturer” or healthcare provider).

Check compliance by the tests of this document.

201.102.2 Labelling

a) The ACCOMPANYING DOCUMENT provided with each VBS, its parts or ACCESSORIES, compliant with 201.102.1, shall include at least one MODEL OR TYPE REFERENCE of compatible VENTILATORY SUPPORT EQUIPMENT.

b) Statements shall be included in the ACCOMPANYING DOCUMENT of each VENTILATOR BREATHING SYSTEM, its parts or ACCESSORIES to the effect that:

1) ventilator breathing systems, their parts and accessories are validated for use with specific ventilators;

2) incompatible parts can result in degraded performance; and

3) the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 Breathing sets

a) Breathing sets, other than heated breathing sets, intended for use in the VBS shall comply with ISO 5367:2014.

b) Heated breathing sets shall comply with ISO 80601-2-74:2017.

Check compliance by application of the tests of ISO 5367:2014 or ISO 80601-2-74:2017, as appropriate.

201.102.4* Humidification

201.102.4.1 HUMIDIFIER

Any HUMIDIFIER, including heated breathing sets, either incorporated into the VENTILATORY SUPPORT EQUIPMENT or recommended for use with the VENTILATORY SUPPORT EQUIPMENT, shall comply with ISO 80601-2-74:2017.

Check compliance by application of the tests of ISO 80601-2-74:2017.

201.102.4.2 HEAT AND MOISTURE EXCHANGER (HME)

Any HME, either incorporated into the VBS or recommended for use with the VBS, shall comply with ISO 9360-1:2000 or ISO 9360-2:2001.

Check compliance by application of the tests of ISO 9360-1:2000 or ISO 9360-2:2001.

201.102.5 BREATHING SYSTEM FILTERS (BSF)

Any BSF, either incorporated into the VENTILATORY SUPPORT EQUIPMENT or recommended for use with the VENTILATORY SUPPORT EQUIPMENT, shall comply with the relevant requirements of ISO 23328-1:2003 and ISO 23328-2:2002.

Check compliance by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.103 * Training

In the application of the requirements of IEC 62366-1:2015, 5.6, 5.7.1 b), 5.7.3 d) and 5.8 training shall be considered necessary for both the LAY OPERATOR and the designee of the RESPONSIBLE ORGANIZATION.

NOTE Requirements for training are found in IEC 62366-1:2015, 5.8.

Check compliance by inspection of the ACCOMPANYING DOCUMENT and the USABILITY ENGINEERING FILE.

201.104 * Indication of duration of operation

a) The VENTILATORY SUPPORT EQUIPMENT shall have means to indicate visually the cumulative hours of operation of the VENTILATORY SUPPORT EQUIPMENT, either:

1) automatically; or

2) by OPERATOR action.

b) The VENTILATORY SUPPORT EQUIPMENT should also have means to indicate visually:

1) the time since the last preventive maintenance; or

2) the time until the next recommended preventive maintenance.

Check compliance by inspection.

201.105 FUNCTIONAL CONNECTION

201.105.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained if connections to the FUNCTIONAL CONNECTION of VENTILATORY SUPPORT EQUIPMENT are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.105.2 * Connection to an electronic health record

VENTILATORY SUPPORT EQUIPMENT should be equipped with a FUNCTIONAL CONNECTION that permits data transmission from the VENTILATORY SUPPORT EQUIPMENT to e.g. an electronic health record.

201.105.3 Connection for remote control

VENTILATORY SUPPORT EQUIPMENT may be equipped with a FUNCTIONAL CONNECTION for connection for remote control of the VENTILATORY SUPPORT EQUIPMENT.

201.106 Display loops

201.106.1 Pressure-volume loops

If VENTILATORY SUPPORT EQUIPMENT is provided with the display of pressure-volume loops,

a) the graph shall use:

   1) DELIVERED VOLUME on the vertical axis; and

   2) AIRWAY PRESSURE on the horizontal axis;

b) positive values shall be on the top and the right of the display;

c) increases in DELIVERED VOLUME shall be positive values;

d) the volume shall be reset to the origin at the beginning of each breath.

Check compliance by inspection.

201.106.2 Flow-volume loops

a) If VENTILATORY SUPPORT EQUIPMENT is provided with the display of flow-volume loops,

   1) the graph shall use:

      i) flowrate on the vertical axis; and

      ii) DELIVERED VOLUME on the horizontal axis;

   2) positive values shall be on the top and the right of the display;

   3) gas flow to the PATIENT (inspiratory flow) and increases in DELIVERED VOLUME shall be positive values;

   4) the volume shall be reset to the origin at the beginning of each breath;

b) the VENTILATORY SUPPORT EQUIPMENT may be provided with an additional optional display configuration for the flow-volume loop where gas flow from the PATIENT (expiratory flow) is represented as a positive value.

Check compliance by inspection.

201.107 Spontaneous breathing during loss of ventilation

a) The VENTILATORY SUPPORT EQUIPMENT shall be designed in such a way as to allow spontaneous breathing when normal ventilation delivery is compromised in NORMAL CONDITION and SINGLE FAULT CONDITION.

EXAMPLES Causes of loss of spontaneous breathing include power supply failure, loss of SUPPLY MAINS, turbine failure.

b) The means to allow spontaneous breathing may be provided by a MASK or ACCESSORY.

c) If the PATIENT cannot breathe ambient air through their mouth while connected to the VENTILATORY SUPPORT EQUIPMENT and the ACCESSORIES, with all recommended ACCESSORIES in place, the inspiratory and expiratory resistance:

1) measured at the PATIENT-CONNECTION PORT shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of 30 l/min; or

2) shall comply with ISO 17510:2015, 5.5.

NOTE These requirements are intended to allow the PATIENT to breathe spontaneously under compromised conditions.

Check compliance by functional testing and measurement of flowrate, pressure, and resistance at the PATIENT-CONNECTION PORT with that combination of ACCESSORIES indicated in the instructions for use which produces the greatest pressure drop.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.4.3.1 * Compliance criteria

Amendment (replace the second dash of 4.3.1 with):

— the VENTILATORY SUPPORT EQUIPMENT operated using the conditions and test configuration of 201.9.6.2.1.101.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Amendment (add note to list element b)):

NOTE The requirements of this document are not considered deviations or allowances.

Additional subclause:

202.8.1.101 * Additional general requirements

a) The VENTILATORY SUPPORT EQUIPMENT shall be tested according to the requirements for the HOME HEALTHCARE ENVIRONMENT.

b) The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, shall not be allowed:

1) component failures;

2) changes in programmable parameters or settings;

3) reset to default settings;

4) change of operating mode;

EXAMPLES Change of breath type, ventilation mode, ventilatory frequency, I:E ratio.

5) initiation of an unintended operation;

6) for volume-controlled breath types, during the testing, the error of:

i) the DELIVERED VOLUME of individual breaths greater shall not deviate by more than 35 %; and

ii) the DELIVERED VOLUME averaged over a one-minute interval shall not deviate by more than 25 %; and

7) for pressure-controlled breath types, during the testing, the error at the PATIENT-CONNECTION PORT shall not deviate by more than twice the AIRWAY PRESSURE accuracy limit disclosed in the instructions for use for:

i) static pressure, or

ii) dynamic pressure.

c) The VENTILATORY SUPPORT EQUIPMENT may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing) that does not adversely affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

206 Usability

IEC 60601-1-6:2010+AMD1:2013 applies except as follows:

For VENTILATORY SUPPORT EQUIPMENT, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) observing monitored ventilation parameters from the intended OPERATOR'S position;

EXAMPLE 1 AIRWAY PRESSURE.

b) configuring the VBS including connection of the detachable parts of the VBS to the VENTILATORY SUPPORT EQUIPMENT;

EXAMPLES 2 HUMIDIFIER, nebulizer, water-trap, tubing, BREATHING SYSTEM FILTER, MONITORING EQUIPMENT.

c) connecting or disconnecting the PATIENT-CONNECTION PORT of the VBS to the PATIENT-interface;

d) PROCESSING the VBS components;

e) starting the VENTILATORY SUPPORT EQUIPMENT from power off;

f) turning off the VENTILATORY SUPPORT EQUIPMENT;

g) carrying the VENTILATORY SUPPORT EQUIPMENT with one hand:

1) either directly, or,

2) by use of a carrying case or in-use bag; and

h) if TRANSIT-OPERABLE, attaching and disconnecting the VENTILATORY SUPPORT EQUIPMENT to prevent unwanted movement during transport while in use.

The following functions, if available, also shall be considered PRIMARY OPERATING FUNCTIONS:

i) performing a basic pre-use functional check of the VENTILATORY SUPPORT EQUIPMENT including the ALARM SYSTEM;

j) setting and inadvertent change of settings of the OPERATOR-adjustable controls:

1) setting ALARM LIMITS;

2) inactivating ALARM SIGNALS;

3) switching between different ventilation modes and breath types;

4) setting ventilation control parameters;

EXAMPLES 3 Ventilatory frequency, PEEP, pressure support, INSPIRATORY TIME or I:E ratio.

k) switching between power sources;

l) connecting and disconnecting the DISTRIBUTED ALARM SYSTEM;

m) testing power sources;

n) starting ventilation from standby; and

o) activating standby.

The following actions associated with ventilation also shall be considered PRIMARY OPERATING FUNCTIONS:

NOTE For the purposes of this document the following functions are considered PRIMARY OPERATING FUNCTIONS even though they are not performed on the VENTILATORY SUPPORT EQUIPMENT'S OPERATOR-EQUIPMENT INTERFACE.

p) humidifying/conditioning gases delivered through the VBS.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies except as follows:

211.7.4.7 Additional requirements for CLEANING, DISINFECTION and STERILIZATION

Amendment (add after 'INTENDED USE, ' in the first paragraph):

in either NORMAL CONDITION or SINGLE FAULT CONDITION,

211.10.1.1 General requirements for mechanical strength

Amendment (add as the first paragraph):

aa) The tests of Clause 10 of IEC 60601-1-11:2015 and 15.3 of IEC 60601-1:2005+AMD1:2012 shall be performed on the same test VENTILATORY SUPPORT EQUIPMENT after the tests of 201.11.6.6 of this document are performed.

bb) If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate VENTILATORY SUPPORT EQUIPMENT may be used for each specified PROCEDURE.

IEC 60601-1:2005+AMD1:2012, annexes, apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Annex C, applies, except as follows:

Addition:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of VENTILATORY SUPPORT EQUIPMENT, its parts and ACCESSORIES are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES

Description of marking	Subclause
Any particular warnings or precautions relevant to the immediate operation of the VENTILATORY SUPPORT EQUIPMENT	201.7.2.101 a) 1)
Arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS, if applicable	201.7.2.101 b) 1)
Containing natural rubber latex, if applicable	201.7.2.13.101 a)
For ACCESSORIES supplied separately, indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, if applicable	201.7.2.4.101 a) 2)
For ACCESSORIES supplied separately, the requirements of 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.101	201.7.2.4.101 a) 1)
For each VBS, part and ACCESSORY, contains phthalates or other substances, if applicable	201.11.7 dd) 1)
For packaging of each VBS, part and ACCESSORY, contains phthalates, if applicable	201.11.7 dd) 2)
For packaging, containing natural rubber latex, if applicable	201.7.2.17.101 a) 3)
For packaging, description of the contents	201.7.2.17.101 a) 1)
For packaging, identification reference to the batch, type or serial number	201.7.2.17.101 a) 2)
Trigger sensitivity control lowest number to represent the setting for the least PATIENT effort, if applicable	201.7.4.2 bb) 1)
Trigger sensitivity control minimum and maximum settings self-evident, if applicable	201.7.4.2 aa)
Trigger sensitivity control not only numeric, if applicable	201.7.4.2 bb) 2)
Warning not to obstruct the GAS INTAKE PORT, if applicable	201.7.2.101 b) 2)

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of VENTILATORY SUPPORT EQUIPMENT or its parts are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general

Description of requirement	Subclause
For each VBS and ACCESSORY, the MODEL OR TYPE REFERENCE of at least one compatible VENTILATORY SUPPORT EQUIPMENT	201.102.2 a)
For each VBS, its parts or ACCESSORIES, a statement to the effect that the responsible organization is accountable for the compatibility of the ventilator and all of the parts and accessories used to connect to the patient before use	201.102.2 b) 3)
For each VBS, part and ACCESSORY, a statement to the effect that ventilator breathing systems, their parts and accessories are validated for use with specific ventilators	201.102.2 b) 1)
For each VBS, part and ACCESSORY, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
List of designated MASKS or ACCESSORIES required to control REBREATHING or the information to locate the list, if required	201.12.4.105 d) 1) ii)
Maximum time-weighted average input flow for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flow for each gas, if applicable	201.4.11.101.2 3) ii)
Name or trade name and address of the MANUFACTURER and where the MANUFACTURER does not have an address within the locale an authorized representative	201.7.9.1
Units of measure for AIRWAY PRESSURE capable of being configured in hPa	201.7.4.3 bb)
Units of measure for volumes, flows and leakages expressed as STPD or BTPS, as appropriate	201.7.4.3 aa)
VENTILATORY SUPPORT EQUIPMENT is a high-flow device warning, if applicable	201.4.11.101.2 3) iii)
Warning statement to the effect that failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation, if applicable	201.12.4.105 d) 1) i)

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for information to be included in the instructions for use of VENTILATORY SUPPORT EQUIPMENT or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Accuracy of expired volume MONITORING EQUIPMENT, if so equipped	201.12.4.102
Alternative SUPPLY MAINS, maximum current required, if so equipped	201.11.8.101.2 a) 4)
Alternative SUPPLY MAINS, means of connection, if so equipped	201.11.8.101.2 a) 1)
Alternative SUPPLY MAINS, NOMINAL voltage range, if so equipped	201.11.8.101.2 a) 3)
Alternative SUPPLY MAINS, RATED voltage range, if so equipped	201.11.8.101.2 a) 2)
Any adverse effect of any recommended ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, if applicable	201.7.9.2.14.101 b)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101 d)

Description of requirement	Subclause
A-weighted sound power level emitted by the VENTILATORY SUPPORT EQUIPMENT	201.9.6.2.1.101 a) 201.9.6.2.1.101 b)
A-weighted sound pressure level emitted by the VENTILATORY SUPPORT EQUIPMENT	201.9.6.2.101 a)
Behaviour of the VENTILATORY SUPPORT EQUIPMENT after a switchover to the INTERNAL ELECTRICAL POWER SOURCE or alternative SUPPLY MAINS	201.11.8.101.1 c) 2)
Behaviour of the VENTILATORY SUPPORT EQUIPMENT while the INTERNAL ELECTRICAL POWER SOURCE or external reserve electrical power source is recharging	201.11.8.101.1 c) 3)
Description of the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging or replacement, if applicable	201.7.9.2.13.101 b)
Description of the periodic visual safety inspections that should be performed by the OPERATOR	201.7.9.2.13.101 a)
Disclosure of any restrictions on the placing of components within the VENTILATOR BREATHING SYSTEM, if applicable	201.7.9.2.14.101 a)
For ACCESSORIES supplied separately where marking the ACCESSORY is not practicable, the requirements of 201.7.2.13.101, 201.7.2.17.101 and 201.7.2.4.101	201.7.2.4.101 b)
For each VBS, part and ACCESSORY containing phthalates or other substances, information on RESIDUAL RISKS for children or treatment of pregnant or nursing women	201.11.7 gg) 1)
For each VBS, part and ACCESSORY containing phthalates or other substances appropriate precautionary measures, if applicable	201.11.7 gg) 2)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions for use, the information contained in instructions for use for LAY OPERATOR	201.7.9.2.1.101 c)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, any limitation of parameter settings	201.7.9.2.9.101.2 a) 5)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, method by which all functions and settings necessary for NORMAL USE can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 b) 1)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, method which can determine whether or not the assembled breathing tubes and related ACCESSORIES are suitable for use	201.7.9.2.8.101 b) 2)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the essential technical characteristics of each recommended BREATHING SYSTEM FILTER, if applicable	201.7.9.2.9.101.2 e) 1)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the intended range of DELIVERED VOLUME	201.7.9.2.9.101.2 b) 2)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the methods for controlling the cycling	201.7.9.2.9.101.2 a) 2)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the parameter settings	201.7.9.2.9.101.2 a) 3)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the range of parameter settings	201.7.9.2.9.101.2 a) 4)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the RATED range of compliance of the assembled OPERATOR-detachable parts of the VBS, over	201.7.9.2.9.101.2 b) 1) iii)

Description of requirement	Subclause
which the accuracies of set and monitored volumes and pressures are maintained	
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the RATED range of inspiratory and expiratory GAS PATHWAY resistances of the assembled OPERATOR-detachable parts of the VBS, over which the accuracies of set and monitored volumes and pressures are maintained	201.7.9.2.9.101.2 b) 1) i) and ii)
For the HEALTHCARE PROFESSIONAL OPERATOR instructions, the working principle of each of the VENTILATORY SUPPORT EQUIPMENT's ventilation modes including waveforms	201.7.9.2.9.101.2 a) 1)
For the LAY OPERATOR instructions, a description of a means to determine the operation time of the INTERNAL ELECTRICAL POWER SOURCE, if provided	201.7.9.2.9.101.1 b) 1)
For the LAY OPERATOR instructions, a description of how to connect a DISTRIBUTED ALARM SYSTEM	201.7.9.2.9.101.1 b) 2)
For the LAY OPERATOR instructions, conditions under which the VENTILATORY SUPPORT EQUIPMENT maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a) 1)
For the LAY OPERATOR instructions, method by which all switchover to and operation from the INTERNAL ELECTRICAL POWER SUPPLY can be functionally tested to determine if they are operating correctly, if provided	201.7.9.2.8.101 a) 2)
For the LAY OPERATOR instructions, method by which the assembled breathing tubes and related ACCESSORIES can be functionally tested to determine if they are operating correctly	201.7.9.2.8.101 a) 1)
For the LAY OPERATOR instructions, the MODEL OR TYPE REFERENCE needed to perform the pre-use check can be performed	201.15.102 c)
For the LAY OPERATOR instructions, the PROCEDURE by which pre-use check can be performed	201.15.102 d)
For VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES would be reused	201.7.9.2.1.102 a)
For VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES intended for single use, intended duration of use	201.7.9.2.1.102 b) 1)
For VENTILATORY SUPPORT EQUIPMENT, its parts or ACCESSORIES intended for single use, consequences for the PATIENT if use is beyond the specified duration of use	201.7.9.2.1.102 b) 2)
Maximum error of the AIRWAY PRESSURE at the end of the expiratory phase in relation to the set value for a pressure-controlled breath in NORMAL CONDITION	201.12.1.102 b) 3)
Maximum error of the AIRWAY PRESSURE at the end of the expiratory phase in relation to the set value under leak for a pressure-controlled breath in NORMAL CONDITION under leak condition	201.12.1.102 b) 4)
Maximum error of the AIRWAY PRESSURE at the end of the inspiratory phase in relation to the set value for a pressure-controlled breath in NORMAL CONDITION	201.12.1.102 b) 1)
Maximum error of the AIRWAY PRESSURE at the end of the inspiratory phase in relation to the set value under leak for a pressure-controlled breath in NORMAL CONDITION under leak condition	201.12.1.102 b) 2)

Description of requirement	Subclause
Maximum error of the DELIVERED VOLUME in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.101 b) 1)
Maximum error of the PEEP in relation to the set value for a volume-controlled breath in NORMAL CONDITION	201.12.1.101 b) 2)
Operational time of the power source when fully charged	201.11.8.101.1 c) 1)
Performance and pass-fail criteria for other breath types in NORMAL CONDITION	201.12.1.103 a)
PROCESSING or reprocessing PROCESS instructions for the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES	201.11.6.6 dd) 2)
Separate instructions for use for HEALTHCARE PROFESSIONAL OPERATOR	201.7.9.2.1.101 a) 2)
Separate instructions for use for LAY OPERATOR	201.7.9.2.1.101 a) 1)
Statement to the effect that do not use the ventilator at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range]. Using the ventilator outside of this temperature range or above this altitude can compromise ventilator performance	201.7.9.2.9.101.1 a) 2)
Statement to the effect that to reduce the likelihood of disconnection and to prevent adverse ventilator performance use only accessories compatible with the ventilator. Compatibility is determined by reviewing the instructions for use of either the ventilator or the accessories	201.7.9.2.9.101.1 a) 3)
Statement to the effect that ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.9.101.1 a) 4)
Summary description of the VENTILATORY SUPPORT EQUIPMENT algorithm for determining the AIRWAY PRESSURE ALARM LIMIT, if provided	201.12.4.101.2 f)
Warning statement to the effect that do not add any attachments or accessories to the ventilator that are not intended for use in combination with the ventilator, as stated in the instructions for use of the ventilator or accessory may not function correctly leading to the risk of degradation or loss of ventilatory support	201.7.9.2.2.101 b)
Warning statement to the effect that do not cover the ventilator or place in a position that affects proper operation, including applicable examples	201.7.9.2.2.101 a)
Warning statement to the effect that the ventilator accuracy can be adversely affected by the gas added by the use of a pneumatic nebuliser, if applicable	201.7.9.2.2.101 c)
Warning statement to the effect that this ventilator is not suitable for a ventilator-dependent patient	201.7.9.2.2.101 d)
Which portions of the GAS PATHWAYS through the VENTILATORY SUPPORT EQUIPMENT can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION	201.7.9.2.12 aa)

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of VENTILATORY SUPPORT EQUIPMENT or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Disclosure of the interdependence of control functions	201.7.9.3.1.101 b)
Disclosure of the uncertainty for each disclosed tolerance	201.5.101.3 b)
Pneumatic diagram of the VENTILATORY SUPPORT EQUIPMENT, including a diagram for OPERATOR-detachable parts of the VENTILATOR BREATHING SYSTEM either supplied or recommended in the instructions for use	201.7.9.3.1.101 c)
Statement to the effect that the RESPONSIBLE ORGANIZATION needs to ensure the compatibility of the VENTILATOR and all of the parts and ACCESSORIES intended to be used to connect to the PATIENT prior to use	201.7.9.3.1.101 e)
Summary description of the filtering or smoothing techniques for all measured or computed variables that are displayed or used for control	201.7.9.3.1.101 a)
Summary description of the means of initiating and terminating the inspiratory phase while the ventilator is operating in each of its ventilatory modes	201.7.9.3.1.101 d)
Summary description of the test method and PROCEDURE to test other breath modes, if provided	201.12.1.103 e)

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005+AMD1:2012, Annex D, applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1	LOT	IEC/TR 60878:2015[15] ISO 7000-2492[16] Symbol 5.1.5 ISO 15223-1:2016	Batch code To identify the MANUFACTURER's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
2	REF	IEC/TR 60878:2015[15] ISO 7000-2493[16] Symbol 5.1.6 ISO 15223-1:2016	Catalogue number To identify the MANUFACTURER's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
3	SN	IEC/TR 60878:2015[15] ISO 7000-2498[16] Symbol 5.1.7 ISO 15223-1:2016	Serial number To identify the MANUFACTURER's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
4	LATEX	IEC/TR 60878:2015[15] ISO 7000-2725[16] Symbol 5.4.5 ISO 15223-1:2016	Contains or presence of [natural rubber latex] On medical devices: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where LATEX is used for natural rubber latex.

5		IEC/TR 60878:2015[15] ISO 7000-2725[16] EN 15986:2011	Contains or presence of [xxx] On medical devices: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.
6		IEC/TR 60878:2015[15] ISO 7000-2725[16]	Contains or presence of [xxx] On medical devices: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 — Scope

There are key contextual differences between home VENTILATORY SUPPORT EQUIPMENT and a VENTILATOR intended for VENTILATOR-DEPENDENT PATIENTS. One difference is the stability of the PATIENT. Another is the balance between ventilation and other important lifestyle functions, such as eating, speaking, psychosocial aspects and general physical activity. When choosing and configuring modes, circuits, and ALARM CONDITIONS, the supervising clinician and PATIENT need to balance the knowledge and certainty of ventilation against the PATIENT'S autonomy and lifestyle.

ISO 80601-2-79 compliant VENTILATORS are used by PATIENTS who require a minimal level of support to provide adequate gas exchange. Without such support, these PATIENTS would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. The most fragile of these PATIENTS would not likely experience injury with the loss of this artificial ventilation.

Additional information is contained in ISO 21954[17].

Subclause 201.4.3.101 — Additional requirements for ESSENTIAL PERFORMANCE

VENTILATORY SUPPORT EQUIPMENT for RESPIRATORY IMPAIRMENT has no ESSENTIAL PERFORMANCE. PATIENTS diagnosed with mild to moderate chronic obstructive pulmonary disease (COPD) are capable of spontaneously breathing and do not require additional ventilation support. In the absence of treatment (e.g. power failure or loss of therapy or other likely/foreseeable events) where performance is lost or degraded beyond the limits specified by the MANUFACTURER, the PATIENT does not suffer any immediate adverse effects requiring immediate medical intervention. The most fragile of these PATIENTS would not likely experience injury with the loss of this artificial ventilation. This means that a loss in performance of VENTILATORY SUPPORT EQUIPMENT for RESPIRATORY IMPAIRMENT does not result in an unacceptable RISK. This is why no ALARM CONDITIONS are required when therapy is lost or degraded.

Nonetheless, VENTILATORY SUPPORT EQUIPMENT for RESPIRATORY IMPAIRMENT is expected to provide effective therapy in NORMAL CONDITION even though loss of that therapy is not considered an unacceptable RISK. This is why pressure is evaluated in lieu of ESSENTIAL PERFORMANCE as an acceptance criterion (i.e. pressure does not change by more than twice the AIRWAY PRESSURE accuracy limit disclosed in the instructions for use).

Subclause 201.4.6 — ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Since much of the VBS is likely to be draped over or around the PATIENT, it is likely to come into direct contact with the PATIENT during NORMAL USE. Additionally, the GAS PATHWAYS conduct fluids into or out of the PATIENT. As such, the GAS PATHWAYS of the VBS and the VENTILATORY SUPPORT EQUIPMENT need to be

investigated regarding BIOCOMPATIBILITY and compatibility with substances that might pass into or out of the PATIENT via the GAS PATHWAYS. Also of concern are electrical HAZARDS should any circuitry be incorporated into the VBS. By ensuring that those items are subject to the requirements for APPLIED PARTS, these issues are addressed by the requirements already in the general standard.

Subclause 201.4.11.101 — Additional requirements for pressurized gas input

VENTILATORY SUPPORT EQUIPMENT designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its RATED range of supply pressures; and these pressures can only be maintained if the VENTILATORY SUPPORT EQUIPMENT in NORMAL CONDITION does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these VENTILATORY SUPPORT EQUIPMENT should be designed to prevent an unacceptable RISK under possible SINGLE FAULT CONDITIONS of the pressurized gas supply.

Pressurized medical gas supplies, including MEDICAL GAS PIPELINE SYSTEMS and cylinder pressure regulators conforming to current relevant standards, supply gas-specific terminal outlets at a pressure that is within an internationally agreed-upon pressure range of 280 kPa to 600 kPa under NORMAL CONDITION. It is expected that VENTILATORY SUPPORT EQUIPMENT should operate to their declared specification at any supply pressure within this range.

In the case of a pressure regulator failure, the gas supply pressure could rise to the pressure regulator's supply pressure, which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered ME EQUIPMENT should be designed so as not to present an unacceptable RISK if its supply pressure rises up to this value. There is a specific requirement that VENTILATORY SUPPORT EQUIPMENT should continue operation with acceptable performance such that PATIENTS can continue to be ventilated until such time as normal operation can be restored or that alternative arrangements can be made.

VENTILATORY SUPPORT EQUIPMENT with maximum RATED input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum RATED input pressure.

Under the SINGLE FAULT CONDITION that the supply pressure of any one gas drops below 280 kPa, under steady-state conditions, it is understood that VENTILATORY SUPPORT EQUIPMENT cannot be expected to continue to operate on this gas. However, it is required that in this case, the VENTILATORY SUPPORT EQUIPMENT should detect the unacceptable low pressure, produce an ALARM SIGNAL and also, in the case of two pressurized gas supplies, automatically switch to use the other gas source (oxygen or air) to supply the VENTILATOR. This requirement is stated in 201.13.101.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, MEDICAL GAS PIPELINE SYSTEMS, supplying compressed medical gases through gas-specific terminal outlets, are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flowrates up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The MEDICAL GAS PIPELINE SYSTEM is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the MEDICAL GAS PIPELINE SYSTEM by the application of a 'diversity factor'; a factor agreed upon between the supplier and RESPONSIBLE ORGANIZATION to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the MEDICAL GAS PIPELINE SYSTEM is capable of supplying an average flowrate of 60 l/min to the required proportion of terminal outlets. However, if the flowrate demand from many adjacent VENTILATORY SUPPORT EQUIPMENT exceeds 60 l/min, there is an increased possibility that the VENTILATORY SUPPORT EQUIPMENT input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

In addition to steady-state flowrates of 60 l/min, the switching of the internal pneumatic subsystem and the operation of a PATIENT demand subsystem can result in VENTILATORY SUPPORT EQUIPMENT requiring transient input flowrates far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize the pressure drop, such transient demands can generally be accommodated from the gas contained locally within the pipe work of the MEDICAL GAS PIPELINE SYSTEM. There can be temporary pressure drops of the input pressure at the inlet of the VENTILATORY SUPPORT EQUIPMENT to below 280 kPa due to transient flowrates in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the MANUFACTURER. MANUFACTURERS need to evaluate their own designs to establish whether any consequent transient pressure drop adversely affects the performance of their VENTILATORY SUPPORT EQUIPMENT when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulators conforming to ISO 10524-1.

VENTILATORY SUPPORT EQUIPMENT that can draw greater average or transient flows during INTENDED USE are permitted, but their ACCOMPANYING DOCUMENTS are required to disclose those flowrates and warn of the need for a different diversity factor.

The average flowrate of 60 l/min is greater than the test flowrate used during the commissioning of MEDICAL GAS PIPELINE SYSTEMS. In itself, this should be of no concern because the conditions specified for the test do not allow a direct comparison between the two values. The subcommittee responsible for pipeline standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flowrate value, and also the 200 l/min for up to 3 s transient flowrates, during the preparation of the first edition of the current series of standards for MEDICAL GAS PIPELINE SYSTEMS and were aware of the need to satisfy that specification when finalizing the MEDICAL GAS PIPELINE SYSTEM test requirements.

MANUFACTURERS should be aware that other medical gas supply system standards permit the fitting of gas-specific terminal outlets to supply systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101 — Additional requirements for general requirements for testing of ME EQUIPMENT

After due consideration, the committees decided that where this document specifies adjoining ranges for variables as the basis for testing and the declaration of performance, the end values of both ranges should be applicable to both ranges. This means that a MANUFACTURER is free to use a round-number end value (e.g. 300 ml) in specifications and is not forced to truncate artificially the declared range in order to avoid having to also satisfy the test requirements of the adjacent range. This permits, for example, one VENTILATORY SUPPORT EQUIPMENT to have a declared range DELIVERED VOLUME of 300 ml to 1000 ml and another 100 ml to 300 ml, with each VENTILATORY SUPPORT EQUIPMENT only being required to be tested for the conditions specified for ≥ 300 ml or ≤ 300 ml respectively.

Subclause 201.5.101.2 — Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (approximately 37 °C) irrespective of the temperature of the gas delivered by VENTILATORY SUPPORT EQUIPMENT. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including VENTILATORY SUPPORT EQUIPMENT, follow engineering conventions and specify gas quantities and flowrates at STPD conditions. This practice is followed in this document for all requirements concerning gas input.

However, VENTILATORY SUPPORT EQUIPMENT complying with this document are likely to be inflating the PATIENT'S lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from

the VENTILATORY SUPPORT EQUIPMENT. With a standard temperature of 0 °C, 1 l of gas referenced to STPD (STANDARD TEMPERATURE PRESSURE DRY) can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different VENTILATORY SUPPORT EQUIPMENT, it is essential that the information for all VENTILATORY SUPPORT EQUIPMENT is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

In VENTILATORY SUPPORT EQUIPMENT a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated.

The necessary corrections also depend on the location of the flow transducer in the VBS. The humidity of the gas can be zero when the transducer measures the inspiratory flow inside the VENTILATORY SUPPORT EQUIPMENT. When, however, the flow transducer is located at the Y-piece, the relative humidity can be anything up to 100 %. When an HME is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the HME. With a blower-based VENTILATORY SUPPORT EQUIPMENT that uses ambient air, the humidity of the drawn-in air can be unknown to the VENTILATORY SUPPORT EQUIPMENT. All these effects together inevitably introduce some errors in the conversion of the measured flow signal to BTPS reference conditions. However, these errors are only in the range of several percent. However, it remains the responsibility of the MANUFACTURER to verify that the accuracy requirements of 201.12.4.101 and 201.12.4.102 are met.

Subclause 201.5.101.3 — VENTILATORY SUPPORT EQUIPMENT testing errors

When testing VENTILATORY SUPPORT EQUIPMENT performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flowrates.

Because of the relative significance of these uncertainties, it is important that MANUFACTURERS allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognize the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a MANUFACTURER determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 % then test acceptance criteria is ±7 %. If a third party is testing to this document, they also need to include measurement uncertainty in their testing. If they subsequently obtain an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester could neither accept nor refuse the MANUFACTURER'S claim.

Furthermore, the MANUFACTURER is required to disclose the measurement uncertainty for each declared value in order to provide both information to the RESPONSIBLE ORGANIZATION and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

b)

The OPERATOR should be aware that only the parts or ACCESSORIES listed in the instructions for use have been VALIDATED by the MANUFACTURER. The use of non-VALIDATED parts can represent an unacceptable RISK.

For example,

— a power supply unit other than the one recommended by the MANUFACTURER can be designed and manufactured with poor quality (bad reliability), can adversely affect the electromagnetic compatibility of the VENTILATORY SUPPORT EQUIPMENT, etc.

— the connection of parts to the VBS that are not listed in the instructions for use may increase the inspiratory or expiratory pathway resistance of the VBS, can increase the unintentional leakage of the VBS, etc. to a level that adversely affects the BASIC SAFETY and ESSENTIAL PERFORMANCE.

c)

The functionality of BREATHING SYSTEM FILTERS is affected by a number of aspects of structure, properties and local environment.

At the most basic, a BSF is designed to be a filter that removes particles suspended in gas, i.e. a “dry aerosol”. The particles primarily targeted in the VBS are bacteria or virus particles (although other particles would be subject to retention). The filtering material (“medium”) is composed of a matrix of solid material with open passageways to allow gas flow. The passageways in such gas filters are relatively large compared to the bacteria and virus particles that are to be removed. The spatial arrangement of the solid part of the filter medium versus the open spaces in the medium brings the particles in proximity to the surfaces of the medium, where physical forces (electrostatic attraction and Van der Waals forces) attract and bind the particles within the matrix, removing them from the gas flow.

In the practical situation of anaesthesia or respiratory care therapy, environmental factors related to the PATIENT, or the therapy can alter the performance of the BSF from that which would occur in the simple flow of air with suspended microorganisms though the BSF.

One major factor is the presence, phase, and amount of moisture present in the gas flowing through the BSF.

When there is low humidity in the gas (gaseous phase moisture) the gaseous water molecules generally pass though the filter medium without effect. If there is a sufficiently high relative humidity, some BSFs can adsorb or absorb part of this humidity.

If the moisture exists as a liquid aerosol, the water droplets can also be retained by the filter.

The properties of a filter medium that govern the degree to which this interaction with water takes place is its relative affinity for water. A medium which readily attracts water is termed “hydrophilic” and a medium which repels water is termed “hydrophobic”. These properties are, in fact, not discrete, but exist on a continuous scale. Nevertheless, in common parlance filters are grouped into being (relatively) hydrophilic or hydrophobic.

Another example of liquid phase water can be termed “bulk water”. An example of this is the collected condensate that occurs in the expiratory limb of the VBS. Depending on the management of the circuit, and the positioning of the BSF, this bulk water can actually completely cover and occlude the filter. If a sufficient pressure is applied, the liquid water can be forced though the pores of the filter medium. This requires relatively low pressure for a hydrophilic filter and relatively high pressure for a hydrophobic filter.

The practical consequences of the latter scenario is that if liquid is forced though a hydrophilic BSF, gas flow blockage can be relieved, but any microorganisms removed by the filter can be carried past the filter with the liquid stream. In the case of a hydrophobic filter, the pressure in the VBS is usually not sufficient to force liquid though the medium, so the microbial retention is not compromised. Airflow occlusion persists, however, until steps are taking to remove the bulk water.

In addition, there can be a temporal aspect to the properties of relative hydrophilicity or hydrophobicity whereby prolonged exposure to water alters these properties during the EXPECTED SERVICE LIFE of the BSF. A BSF is typically labelled with an EXPECTED SERVICE LIFE, in hours or days, that reflects its ability to perform to its labelled specifications in the clinical environment.

It should be obvious that the potential influence of water on performance differs in anaesthesia and respiratory care applications, although many, if not most, BSFs are indicated for use in both applications.

Additional effects on BSF functionality can be caused by the introduction of substances other than water or gas into the device. Such substances can originate from the PATIENT (e.g. sputum, exudates, blood, vomitus) or substances introduced by the OPERATOR into the VBS (e.g. medications intended to be nebulised for administration though the VBS).

The effect of such substances can be an increase in flow resistance of varying degree up to complete occlusion at the VENTILATORY SUPPORT EQUIPMENT or physiologic pressures. In the case of nebulised medications, the type of nebuliser, and its operating parameters are variables that affect the likelihood or magnitude of significantly increased BSF flow resistance during a prescribed medication regimen. It should be mentioned that accidental introduction of gross amounts of medication from the nebuliser reservoir during OPERATOR or PATIENT manipulation of the VBS has been implicated as a source of acute BSF blockage.

The cause of increased flow resistance in a BSF can be gross blockage of the medium passages, or the effects of surfactant properties of the substances introduced into the BSF upon the hydrophobicity of the filter medium. It should be noted that medications indicated for nebulisation can contain surfactant materials that are not identified in the medications' labelling with respect to their presence or their quantity, and these can change without notice for a given medication. The effect of these substances upon flow resistance differs among individual models and brands of BSFs.

The OPERATOR needs to be aware that the effects of such substances can be manifested as increases in the amount of positive AIRWAY PRESSURE required for a VENTILATORY SUPPORT EQUIPMENT-provided breath, or as an increase in expiratory flow resistance, resulting in a step-wise increase in intrapulmonary pressure that, if not detected, can lead to pneumothorax.

Awareness of the possibility, albeit infrequent or rare, of such significant increases in BSF flow resistance, and inclusion in a trouble-shooting scheme for this and other causes of impaired ventilation can reduce or eliminate adverse events occurring secondary to BSF flow occlusion.

Direct PATIENT monitoring, and usage of the appropriate settings for, and prompt attention to, VENTILATORY SUPPORT EQUIPMENT ALARM CONDITIONS are essential to provide maximum PATIENT safety.

Once a BSF is recognized to be a source of impaired ventilation, simply removing the occluded BSF and replacing it with another BSF returns ventilation to a normal state.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up procedure

In some designs, adequate checking of the ALARM SYSTEM can be performed with a combination of OPERATOR action and the power-on self-test routines that verify the integrity of the software and the integrity of the computer controlling the VENTILATORY SUPPORT EQUIPMENT, as well as the measuring sensors and the ALARM SIGNAL generation.

Subclause 201.7.9.2.9.101 — Additional requirements for operating instructions

Some VENTILATORY SUPPORT EQUIPMENT is designed so that they can operate with higher-than-normal tubing circuit compliance and resistance. Thus knowledge of these VBS characteristics is important for the OPERATOR to be aware of the VENTILATORY SUPPORT EQUIPMENT capability. Also, knowledge of the maximum VBS resistance (at NOMINAL and maximum flowrates) is important because an occlusion FALSE POSITIVE ALARM CONDITION can be caused by the use of high-resistance components in the VBS. These characteristics of the VBS need to be inclusive of any inhalation and exhalation particle/bacteria filters, HUMIDIFIER, nebuliser, water collection vessels and connectors needed for operation.

Subclause 201.7.9.2.14.101 — Additional requirements for ACCESSORIES, supplementary equipment, used material

The use of antistatic or electrically conductive materials in the VBS is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the RISK of electrical shock to the PATIENT.

Subclause 201.7.9.3.1.101 — Additional general requirements

The MANUFACTURER is expected to express the description of the VENTILATORY SUPPORT EQUIPMENT in general terms so the reader can understand the important behaviour of the VENTILATORY SUPPORT EQUIPMENT (e.g. mean values and their time specifications, number of breaths and delays etc.). Some items (e.g. pressures) that one would find in the instructions for use of a life-sustaining VENTILATOR are placed in the technical description for home-use VENTILATORY SUPPORT EQUIPMENT as that information is not expected to be meaningful to the LAY OPERATOR, but is necessary for the HEALTHCARE PROFESSIONAL OPERATOR.

Subclause 201.11.1.2.2 — APPLIED PARTS not intended to supply heat to a PATIENT

The objective of this requirement is to protect the PATIENT from skin burns due to contact with the external surface of the BREATHING TUBE.

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without HARM to the respiratory tract[18]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract[19]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (265,6 kJ/kg) for 45 min[20].

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a heated HUMIDIFIER in clinical practice, the delivered gas energy limit of 197 kJ/ m^3 of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen / air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,9786 m^3/kg of dry air and an enthalpy content of 197 kJ/m^3 of dry air. Assuming the volume breathed by the PATIENT is the same, whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/m^3 of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the PATIENT.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells[21]. This is confirmed by studies conducted by the US. Navy Medical Research and Development Command[19], which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) does not transfer thermal energy to or from the PATIENT with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) draws heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 130 kJ/kg of dry gas breathed by the PATIENT.

Subclause 201.11.6.6 — CLEANING and DISINFECTION of ME EQUIPMENT or ME SYSTEM

The ESSENTIAL PRINCIPLES of ISO 16142-1:2016 require that medical devices are "not [to] compromise the clinical condition or the safety of PATIENTS, or the safety and health of users or, where applicable, other persons, provided that any RISKS which may be associated with their use constitute acceptable RISKS when weighed against benefits to the PATIENT and are compatible with a high level of protection of health and safety."

This means that VENTILATORY SUPPORT EQUIPMENT, their ACCESSORIES and parts should not be used if there is an unacceptable RISK of the PATIENT, OPERATOR or other person being infected as a result of contact with the VENTILATORY SUPPORT EQUIPMENT, ACCESSORY or part.

Therefore after long-term use in the home, VENTILATORY SUPPORT EQUIPMENT, their ACCESSORIES and parts, if transferred to a new PATIENT, require an appropriate level of DISINFECTION, depending on their use, but rarely need to be sterile.

Recommendations for hygienic PROCESSING of VENTILATORY SUPPORT EQUIPMENT, their ACCESSORIES and parts are based on the general hygiene requirements for the PROCESSING of medical devices and need to take

into consideration the special requirements and needs of PATIENT care in the clinical environment. The requirements for hygienic PROCESSING of this standard are intended to:

— make the RESPONSIBLE ORGANIZATION for PROCESSING the VENTILATORY SUPPORT EQUIPMENT aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the PROCESSING of VENTILATORY SUPPORT EQUIPMENT, their ACCESSORIES and parts to comply with the MANUFACTURER'S instructions.

The CLEANING and DISINFECTION PROCEDURES of the MANUFACTURER are also intended to provide practical support to all those involved in PATIENT care in the clinical environment with regard to implementing the hygiene measures required for the PATIENT'S safety.

It should be noted that VENTILATORY SUPPORT EQUIPMENT, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any VENTILATORY SUPPORT EQUIPMENT that has already been used on another PATIENT is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and PROCESSING PROCEDURES are essential to protect the next person handling the device or the next PATIENT on whom the device is used. Hence, VENTILATORY SUPPORT EQUIPMENT, their re-usable ACCESSORIES and parts that have been used are required to undergo a PROCESSING PROCESS, following the MANUFACTURER'S instructions, prior to reuse by another PATIENT.

The following basic considerations need to be addressed by the MANUFACTURER when specifying the PROCESSING instructions of VENTILATORY SUPPORT EQUIPMENT, its ACCESSORIES or parts:

— protecting the PATIENT, the OPERATOR and the RESPONSIBLE ORGANIZATION (including personnel involved in performing the PROCESSING PROCESS);

— the limits of the PROCEDURES used for PROCESSING (such as the number of PROCESSING cycles); and

— the necessity to guarantee the proven standardised PROCEDURES to a consistently high and verifiable quality, based on an established quality management system.

The recommended PROCESSING PROCESS should be determined by:

— the potential degree and type of contamination of the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts; and

— the RISK of infecting another PATIENT resulting from their reuse and the type of application of the VENTILATORY SUPPORT EQUIPMENT.

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S re-breathing under SINGLE FAULT CONDITION should be considered.

On the basis of the above, a VERIFIED and VALIDATED documented PROCESSING PROCEDURE needs to be specified in such detail so that the outcome is reproducible. An acceptable RESIDUAL RISK from the HAZARD of infection for the next PATIENT can be assumed if the:

— documented PROCESSING PROCEDURE'S effectiveness has been VERIFIED through appropriate scientific methods by the MANUFACTURER; and

— reliability of the documented PROCESSING PROCEDURES has been VERIFIED in practice through appropriate quality assurance measures by the RESPONSIBLE ORGANIZATION carrying out the PROCESSING PROCEDURES.

When selecting and evaluating the PROCESSING PROCEDURES, the MANUFACTURER should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts;

— the RISK for the pathogenic microorganisms to be transmitted to the PATIENT, OPERATOR or other persons; and

— the microorganism's resistance to the recommended PROCESSING PROCEDURES.

The RISKS posed by a reprocessed VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts are determined by the following factors:

a) undesired effects, which can result from:

 — the previous use,

 — the previous PROCESSING PROCESSES, and

 — transportation and storage;

b) the RISKS from subsequent uses, such as the following:

 — residues from the previous use (such as secretions, other body fluids, and drugs),

 — residues from the previous PROCESSING PROCESSES (such as CLEANING agents, disinfectants and other substances, including their reaction products),

 — changes of physical, chemical or functional properties of the device, and

 — changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the RISK of transmission of any pathogenic microorganisms.

When considering the suitability of the PROCESSING PROCESS and the feasibility of the PROCESSING PROCESS for the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts, the MANUFACTURER should consider the following points:

— the RISKS involved in the PROCESSING PROCESS;

— the cost effectiveness of the PROCESSING PROCESS;

— the practicability of the PROCESSING PROCESS;

— the availability of the CLEANING equipment and the CLEANING agents specified in the PROCESSING PROCESS;

— the efficiency of the PROCESSING PROCESS;

— the reproducibility of the PROCESSING PROCESS;

— quality management requirements of the PROCESSING PROCESS; and

— the environmental impact of the PROCESSING PROCESS and the disposal of the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts.

The MANUFACTURER should verify all CLEANING agents and PROCESSING PROCEDURES used with regard to their suitability and repeatability with the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts, depending on the type of use.

The RESPONSIBLE ORGANIZATION should verify that manual CLEANING and DISINFECTION of the VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts are always carried out in accordance with the PROCEDURES specified in the ACCOMPANYING DOCUMENT.

The MANUFACTURER should specify VALIDATED automated CLEANING and DISINFECTION PROCEDURES. If they are not followed, the effectiveness of the CLEANING and DISINFECTION cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of CLEANING agents and disinfectants, and residence time.

To ensure the reproducibility of automated PROCESSING PROCEDURES, tests should be carried out on a regular basis.

The MANUFACTURER should ensure that the specified DISINFECTION PROCEDURES are VERIFIED to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected VENTILATORY SUPPORT EQUIPMENT, ACCESSORIES or parts do not pose an unacceptable RISK of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next PATIENT, OPERATOR or person.

Effective DISINFECTION requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any PROCESSING PROCEDURE, safety and functional testing of the VENTILATORY SUPPORT EQUIPMENT (as specified by the MANUFACTURER'S instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the VENTILATORY SUPPORT EQUIPMENT.

The extent and type of the tests depends on the VENTILATORY SUPPORT EQUIPMENT, ACCESSORY or part and these need to be defined in the ACCOMPANYING DOCUMENT.

Subclause 201.12.4.101 — Measurement of AIRWAY PRESSURE

The site in the VBS at which pressure is sensed varies from VENTILATORY SUPPORT EQUIPMENT to VENTILATORY SUPPORT EQUIPMENT. Generally, the MANUFACTURER chooses one of two strategies:

— measuring the AIRWAY PRESSURE by direct sampling at the PATIENT-CONNECTION PORT; or

— indirectly estimating the pressure at the PATIENT-CONNECTION PORT by measuring the pressures at two locations in the VENTILATORY SUPPORT EQUIPMENT: on the inspiratory side of the VBS (at the "to PATIENT" port) and on the expiratory side of the VBS (at the "from PATIENT" port), and, after mathematical manipulation, averaging the two values.

Subclause 201.12.4.103 — MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

The value chosen for the MAXIMUM LIMITED PRESSURE[23] is a compromise between the need to avoid barotrauma and the need to provide an adequate range of pressure to meet the desire of OPERATORS specifically to supply high insufflation pressures for PATIENTS with low chest wall compliance.

Considering the fact that this VENTILATORY SUPPORT EQUIPMENT is used with an open VBS (e.g. leaky MASKS), the committees considered that only one set of maximum pressure limitation for NORMAL CONDITION and SINGLE FAULT CONDITION should be specified. The value chosen was the same as that for which had been in ISO 10651-6.

Subclause 201.12.4.105 — CO_2 rebreathing

MASKS and other PATIENT interfaces intended for use with VENTILATORY SUPPORT EQUIPMENT without an active exhalation valve incorporate an EXHAUST PORT. The function of the EXHAUST PORT is to allow for passive removal of exhaled gases to minimize REBREATHING.

A critical issue to be considered is whether the machine-PATIENT flow through the EXHAUST PORT has reduced the residual exhaled CO_2 to acceptable levels.

VENTILATORY SUPPORT EQUIPMENT can be equipped with a single-conduit BREATHING GAS PATHWAY with a dual-purpose, inspiratory/expiratory function and an EXHAUST PORT. The issue of CO_2 REBREATHING will be a function of several variables, such as the following:

— the type of the breathing attachment — face MASK, nasal MASK, or full face MASK;

— the size and location of the EXHAUST PORTS;

— the average flowrate at the minimum continuous positive AIRWAY PRESSURE;

— the duration of the PATIENT'S exhalation.

There is the potential for clinically significant CO_2 REBREATHING if the EXHAUST PORTS are not designed and located appropriately. Therefore, the design and configuration of VENTILATORY SUPPORT EQUIPMENT and its MASKS and ACCESSORIES has a major impact on the potential for REBREATHING of carbon dioxide and thereby the inspired oxygen concentration.

The maximum recommended time-weighted average for inspired CO_2 in industry is 1 %. An inspired CO_2 fraction of 1 % would add 1 013,25 Pa (7,6 torr) to the test model in ISO 17510:2015, Annex F, and would result in the test end-tidal CO_2 value of 1 013,25 Pa (7,6 torr) + 5 066,25 Pa (38 torr) or 6 079,5 Pa (45,6 torr). This represents a 20 % increase in the CO_2 level. Based on this, the committees chose a 20 % increase in the CO_2 level NORMAL CONDITION limit. Similarly, the 60 % increase in the CO_2 level SINGLE FAULT CONDITION limit represents a time-weighted average for an inspired CO_2 of 3 %.

Subclause 201.13.2.101 — Additional specific SINGLE FAULT CONDITIONS

Operation of VENTILATORY SUPPORT EQUIPMENT without an OPERATOR-detachable BREATHING SYSTEM FILTER in place is considered reasonably foreseeable when considering those parts of the VBS that might become contaminated with body fluids or microbial material conveyed by the expired gases. If VENTILATORY SUPPORT EQUIPMENT can operate without the BREATHING SYSTEM FILTER, then one must assume that it has been operated without the BREATHING SYSTEM FILTER and therefore those parts of the VBS have been contaminated. Additional information is also found in the rationale for 201.11.6.6.

Subclause 201.13.2.102 — Independence of ventilation control function and related RISK CONTROL measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

Subclause 201.101.1.1 — General

Non-standard VBS connectors can represent an unacceptable RISK as attempts are made to fit a VBS to VENTILATORY SUPPORT EQUIPMENT in an emergency. Non-standard VBS connectors can cause leaks if used with similar but not compatible connectors.

The use of Luer taper or Luer-lock connectors complying with ISO 80369-7 are not permitted for use in connection to the GAS PATHWAYS of a VBS as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

Subclause 201.101.1.2.3 — MANUAL VENTILATION PORT

Although provision for the manual ventilation of the PATIENT in cases of emergency is strongly encouraged, the committees decided that this should be by means of a connection into the detachable part of the VENTILATOR BREATHING SYSTEM or at the PATIENT-CONNECTION PORT. It was decided that the use of a connection port on the VENTILATORY SUPPORT EQUIPMENT could lead to misuse or confusion, with no compensating advantage.

Subclause 201.102.1 — General

It is the responsibility of the MANUFACTURERS of a VENTILATOR BREATHING SYSTEM, its parts or ACCESSORIES to verify that their product complies with the requirements of this document by testing their product, in

combination with the other items for which compatibility is claimed, to the requirements of this document.

Subclause 201.102.4 — Humidification

Water management refers to the complete PROCESS by which moisture, in the form of water vapour, is added to the breathing gas delivered to the PATIENT'S lungs and the PROCESS by which humidified breathing gas is conducted back to the VENTILATORY SUPPORT EQUIPMENT'S expiratory subsystem and exhausted to the room. Intrinsic to this PROCESS is the necessity to remove bulk water due to condensation of moisture attributable to temperature changes in the VBS. Even if breathing gas reaches the PATIENT-CONNECTION PORT without any added moisture, the expired breathing gas directed back to the VENTILATORY SUPPORT EQUIPMENT contains a finite quantity of moisture. Water management in the VBS requires attention, whether or not the VBS contains an active HUMIDIFIER, with or without heated wires in the inspiratory or the expiratory limbs of the VBS, or a passive or an active HME at the PATIENT-CONNECTION PORT.

Proper management of the PATIENT'S airway secretions and mucociliary transport system requires that the VENTILATORY SUPPORT EQUIPMENT compensate for the humidity deficit caused by intubation, which bypasses the upper airways where the normal humidification PROCESS would begin. Excess moisture delivered to the PATIENT-CONNECTION PORT can flood the cilia located in the bronchial airways, diminishing their ability to move mucus toward the trachea. On the other hand insufficient humidification of the inspired breathing gas dries the bronchial airways, which leads to thickening of the mucous secretions and likely increased airway resistance or worse. A balanced approach to humidification is needed to maintain healthy cilia. Liquefied mucus can be readily aspirated using a SUCTION CATHETER.

Optimal humidification of the PATIENT'S airways results from an understanding of the physics of the techniques chosen to add water vapour to the inspiratory gas stream. Depending on the VBS selected for delivering humidified breathing gas to the PATIENT (for example, an active vapour HUMIDIFIER with or without heated wires, conventional HME or active HME), condensate can accumulate in the inspiratory limb of the VBS. If condensation occurs, the VBS needs to provide a method by which the liquid can be removed.

In all but the most unusual circumstances, gas leaving the alveoli is saturated at 37 °C. Rainout persists as the moist gas cools and moves toward the PATIENT-CONNECTION PORT, and is conducted back to the VENTILATORY SUPPORT EQUIPMENT. If an HME is fitted at the PATIENT-CONNECTION PORT, approximately 50 % to 70 % of the water vapour will be trapped in the HME. Whatever the configuration of the expiratory limb of the VBS, the water vapour content of the exhaled gas is significant, nearing saturation. Without heated wires, the returning gas cools, causing significant condensation. As in the inspiratory limb, this liquid needs to be removed. The presence of heated wires in the expiratory limb lessens or eliminates condensation before the expired gas enters the GAS RETURN PORT of the VENTILATORY SUPPORT EQUIPMENT, but from this point to the EXHAUST PORT the gas tends to cool further, so more moisture condenses. The VBS needs to include some means to manage this additional condensed water.

Subclause 201.103 — Training

The modern VENTILATORY SUPPORT EQUIPMENT is complex equipment whose use requires specific training for each MANUFACTURER'S make and model. Different MANUFACTURERS often refer to similar modes of ventilation by different names, and, although in principle those modes are similar to those of another MANUFACTURER'S VENTILATORY SUPPORT EQUIPMENT, their modes are unique in sometimes minor and sometimes complex ways. It is essential, therefore, that the LAY OPERATOR and every person involved with its operation and setup of VENTILATORY SUPPORT EQUIPMENT is fully trained in that VENTILATORY SUPPORT EQUIPMENT'S operational characteristics, in particular its controls, capabilities and limitations, prior to any use.

Subclause 201.104 — Indication of duration of operation

VENTILATORY SUPPORT EQUIPMENT require maintenance for continued safe use. A practicable means to ensure that this information is available to the OPERATOR or the RESPONSIBLE ORGANIZATION is to require that the VENTILATORY SUPPORT EQUIPMENT keep track of how long it has been in operation.

Subclause 201.105.2 — Connection to electronic health record

Electronic documentation of PATIENT care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual PATIENT through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. Providing remote supervisory capability is rapidly becoming the standard of care in the HOME HEALTHCARE ENVIRONMENT.

Subclause 202.4.3.1 — Compliance criteria and

Subclause 202.8.1.101 — Additional general requirements

It is not the intent of the committees to require that the IMMUNITY tests be performed multiple times (e.g. with volume-controlled breath type and pressure-controlled breath type at several DELIVERED VOLUMES), but that the MANUFACTURER should determine which breath type and DELIVERED VOLUME represents the worst case for a given IMMUNITY test and use those conditions.

Given the typical use models for this equipment and relative stability of PATIENTS for which this equipment is intended, the committees considered AIRWAY PRESSURE accuracy and DELIVERED VOLUME accuracy as the appropriate parameter to monitor during IMMUNITY tests.

Annex BB
(informative)

Data interface requirements

BB.1 Background and purpose

Heightened interest in the monitoring of VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT, as well as accountability and responsiveness of the parties involved has become evident on an international scale. Consequently, PATIENTS, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of this type of VENTILATORY SUPPORT EQUIPMENT. This trend is also driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the ventilatory performance of the VENTILATORY SUPPORT EQUIPMENT, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of parameters for VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT. The selection is based on some agreement about what is to be monitored, and for what purpose.

It is important to note that any data collection needs to be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted therapy indicators for VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT not only fosters increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT is intended to help to eliminate the current shortcomings and contribute significantly to the improvement of the therapy. This approach seeks to provide a definition that can used across VENTILATORY SUPPORT EQUIPMENT therapy systems for providing therapy data independent of VENTILATORY SUPPORT EQUIPMENT MANUFACTURER or what mechanisms are used to transport the data, either locally or remotely to a HEALTHCARE PROFESSIONAL. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a PATIENT situation. It also provides for flexible and cost-effective integration into disparate software systems that HEALTHCARE PROFESSIONALs can use for PATIENT data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet the needs of PATIENTS, caregivers, clinicians, service providers, and payers. As such, the definition of specific equipment communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this document.

A number of monitoring requirements exist for VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT, depending on the needs of the PATIENT, caregiver, clinician, service provider, and payer, which require various levels of data. This document seeks to define the data that for VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT are required to provide to meet the objectives of these users.

The following levels of data are defined:

— **Parameters and units of measurement:** Parameters and units of measurement used in the VENTILATORY SUPPORT EQUIPMENT;

— **Equipment identification:** Information identifying the VENTILATORY SUPPORT EQUIPMENT;

— **Usage monitoring:** Data providing monitoring of the ventilation;

— **Equipment settings:** The different therapy modes provided by VENTILATORY SUPPORT EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT that require different settings;

— **Ventilation monitoring:** Settings relating to monitoring of PATIENT ventilation;

— **VENTILATORY SUPPORT EQUIPMENT ALARM LIMITS:** Settings relating to ventilation-related ALARM LIMITS;

— **Event information:** Information provided about events related to the usage of the VENTILATORY SUPPORT EQUIPMENT;

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES.

All VENTILATORY SUPPORT EQUIPMENT should provide the information to enable identification of the VENTILATORY SUPPORT EQUIPMENT. Implementation of any further data levels is optional.

Information identifying pressure units used in the data set should also be provided.

BB.2 Data definition

Table BB.101 defines information, which identifies the pressure and flowrate units in the data set.

Table BB.101 — Parameters and units of measurement

Parameter	Description	Type
Pressure units	Specification of the units of measurement for pressure-related data	Value: (cmH_2O or hPa)
Flowrate units	Specification of the units of measurement for flowrate-related data	Value: (l/min or l/s)
Volume units	Specification of the units for flow-related data	Value: (ml or l)
Frequency units	Specification of the units for frequency	Value: (breaths/min)
INSPIRATORY TIME units	Specification of the units for INSPIRATORY TIME	Value: (s)
Leakage units	Specification of the units for leakage	Value: (ml/min or l/min or %)

Table BB.102 defines VENTILATORY SUPPORT EQUIPMENT identification data.

Table BB.102 — Equipment Identification

Parameter	Description	Type
Equipment MANUFACTURER	Identification of the MANUFACTURER of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment serial number	Identification number of the equipment	Text string
Equipment software version	Identification of the software version(s) implemented in the equipment	Text string
NOTE More than one software version might need to be communicated from the equipment.		

Table BB.103 defines data required for usage monitoring.

A set of measured and calculated values should be provided for each therapy session, where a therapy session is any period of time the VENTILATORY SUPPORT EQUIPMENT is providing ventilation.

Table BB.103 — Usage monitoring

Parameter	Description	Type
Therapy start date/time	The current UTC (Coordinated Universal Time) date and time when the usage session was started	ISO 8601 Date Time (YYYY-MM-DDThh:mm:ss)
Therapy stop date/time	The current UTC date and time when the usage session was stopped	ISO 8601 Date Time (YYYY-MM-DDThh:mm:ss)
Hours of ventilation	Number of hours the equipment is powered on and providing ventilation	Value: (h)
Hours of patient use	Number of hours the equipment is providing therapy to the PATIENT for the usage of the current session	Value: (h)

Table BB.104 defines applicable current settings of the VENTILATORY SUPPORT EQUIPMENT for each mode of operation.

Table BB.104 — Equipment settings

Parameter	Description	Type
Mode of operation	Equipment breathing therapy mode as defined within the document	Mode selected: (MANUFACTURER-defined)
PATIENT category	Selected application category	Mode selected: paediatric, adult)
VENTILATOR BREATHING SYSTEM (VBS)	Type of breathing tube used	List of text strings (MANUFACTURER-defined)
MASK	Identification of the user interface language setting	List of text strings (MANUFACTURER-defined)
Language	Identification of the user interface language setting	Selection of supported languages using the language codes given in ISO 639-1[24]
Display brightness	Setting of the luminous intensity as a percentage of the maximum setting	Decimal

Parameter	Description	Type
Inspiratory therapy pressure	Setting of the inspiratory pressure	Value: (cmH_2O or hPa)
Expiratory therapy pressure	Setting of the expiratory pressure	Value: (cmH_2O or hPa)
Inspiratory trigger sensitivity mode	Setting of the inspiratory trigger type 1 = auto 2 = pressure 3 = flow 4 = time 5 = MANUFACTURER-specific	Mode selected: (1, 2, 3, 4, 5)
Inspiratory trigger sensitivity	Inspiratory trigger value by mode	Value: 1 (none) 2 (cmH_2O or hPa) 3 (l/min or %) 4 (ms or %) 5 (List of text strings MANUFACTURER-defined)
Expiratory trigger sensitivity mode	Setting of the expiratory trigger type 1 = auto 2 = pressure 3 = flow 4 = time 5 = MANUFACTURER-specific	Mode selected: (1, 2, 3, 4, 5)
Expiratory trigger sensitivity	Expiratory trigger value by mode	Value: 1 (none) 2 (cmH_2O or hPa) 3 (l/min) 4 (ms or %) 5 (List of text strings MANUFACTURER-defined)
Tidal volume	Setting of the inspiratory tidal volume	Value: (ml)
Inspiratory flow waveform	Setting of the inspiratory flow waveform	List of text strings (MANUFACTURER-defined)
Inspiratory slope	Setting of the inspiratory slope	List of text strings (MANUFACTURER-defined)
PEEP	POSITIVE END-EXPIRATORY PRESSURE	Value: (cmH_2O or hPa)
Breathing frequency	Setting of the frequency of the ventilatory cycle	Value: (breaths/min)
I:E ratio	Setting of the ratio of the inspiratory/expiratory duration	Value: (I:E)
INSPIRATORY TIME	Setting of the duration of the inspiratory part of the cycle	Value: (s)
Inspiratory percentage of the inspiratory cycle	Setting of the percentage of the inspiratory part of the complete ventilatory cycle	Value: (%)
Maximum inspiratory therapy pressure	Setting of the maximum inspiratory breathing therapy pressure	Value: (cmH_2O or hPa)

Table BB.105 defines the indicators relating to monitoring of PATIENT ventilation.

Table BB.105 — Ventilation monitoring

Parameter	Description	Type
Peak inspiratory pressure	Highest pressure during the inspiratory phase of the breathing cycle	Value: (cmH_2O or hPa)
PEEP	POSITIVE END-EXPIRATORY PRESSURE	Value: (cmH_2O or hPa)
FiO_2	Inspiratory oxygen concentration	Value: (% O_2 V/V)
Inspiratory tidal volume	Inspiratory tidal volume delivered by the VENTILATORY SUPPORT EQUIPMENT	Value: (ml)
Expiratory tidal volume	Expiratory tidal volume delivered by the VENTILATORY SUPPORT EQUIPMENT	Value: (ml)
Inspiratory minute volume	Inspiratory minute volume delivered by the VENTILATORY SUPPORT EQUIPMENT	Value: (ml)
Expiratory minute volume	Expiratory minute volume delivered by the VENTILATORY SUPPORT EQUIPMENT	Value: (ml)
Respiratory frequency	Frequencyof respiratory breathing cycles delivered by the VENTILATORY SUPPORT EQUIPMENT	Value: (cycles/min)
INSPIRATORY TIME	Duration of the inspiratory part of the cycle	Value: (s)
I:E ratio	Ratio of the inspiratory/expiratory duration	Value: (I:E)
Leak	Percentage of the Inspiratory volume lost to atmosphere	Value: (l/min or %)
Average pressure	Average pressure of a complete respiratory breathing cycle	Value: (cmH2O or hPa)

Table BB.106 defines applicable VENTILATORY SUPPORT EQUIPMENT usage information.

Table BB.106 — Event information

Parameter	Description	Type
Power supply source	Current source of electrical power 1 = external AC SUPPLY MAINS 2 = INTERNAL ELECTRICAL POWER SOURCE 3 = external DC SUPPLY MAINS	Mode in use: (1, 2, 3)
ALARM SIGNAL inactive state present	List of text strings (ALARM OFF, ALARM PAUSED, AUDIO OFF, AUDIO PAUSED, ACKNOWLEDGED)	List of text strings
Active ALARM CONDITION	Currently active ALARM CONDITIONS	List of text strings (MANUFACTURER-defined)
Access mode	Current access mode of the VENTILATORY SUPPORT EQUIPMENT 1 = LAY OPERATOR 2 = HEALTHCARE PROFESSIONAL OPERATOR 3 = RESPONSIBLE ORGANIZATION	Mode in use: (1, 2, 3)

Table BB.107 defines applicable service and maintenance parameters.

Table BB.107 — Service monitoring

Parameter	Description	Type
Maintenance needed	A MANUFACTURER-specific list of any items requiring maintenance, e.g. filter, blower	List of text strings (MANUFACTURER-defined)
VENTILATORY SUPPORT EQUIPMENT service indicator	An indication that service is required	Text string: (MANUFACTURER-defined)
Hours of ventilation	Number of hours the equipment is powered on and providing ventilation	Value: (h)

Annex CC
(informative)

Reference to the ESSENTIAL PRINCIPLES

This document has been prepared to support the ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE of VENTILATORY SUPPORT EQUIPMENT, its ACCESSORIES or parts as medical devices according to ISO 16142-1:2016. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific ESSENTIAL PRINCIPLES of ISO 16142-1:2016. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the ESSENTIAL PRINCIPLES of ISO 16142-1:2016.

Table CC.1 — Correspondence between this document and the ESSENTIAL PRINCIPLES

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Annex B	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks /notes
1	All	The part relating to manufacturing is not addressed.
a)	201.12.1, 201.12.2.101, 206	
b)	201.12.1, 201.12.2.101, 206	
2	201.4	The part relating to manufacturing is not addressed.
a)	all	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.7, 201.11, 201.12, 201.13, 208	
d)	201.7	
3	all	The part relating to manufacturing is not addressed.
4	all	
5	201.4, 201.15, 211	
6	201.4	
8.1	201.11	
a)	201.11	
b)	201.4, 201.11	
c)	201.9, 201.15	
8.3	201.11	
8.2	201.11	
8.4	201.11	
8.5	201.11, 211	
9.1	201.11, 211	
12.1	201.7, 201.14, 201.16, 201.101, 201.102	

12.2	—	
a)	201.9, 201.11, 201.12.1, 201.12.2.101, 206, 208, 211	
b)	201.12.1, 201.12.2.101, 206, 211	
c)	202, 211	
d)	201.11	
e)	201.14, 201.16, 201.105	
f)	201.11	
g)	202	
12.4	201.11	
12.5	201.7, 201.8	
12.6	201.1.3	
13.1	201.12.1, 201.102	
13.2	201.7, 201.12.1	
13.3	201.7, 201.12.1, 201.12.2.101, 201.12.4, 201.102, 206, 208	
13.4	201.7.4.3	
14.1	201.10	
14.3	201.10	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13	
16.2	211	Only addressed for the HOME HEALTHCARE ENVIRONMENT and EMS ENVIRONMENT.
16.3	201.11.8.101	
16.4	201.11.8.101, 201.12.4, 201.13.101, 208	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9	
17.2	201.9	
17.3	201.9	
17.4	201.15	
17.5	201.9, 201.101	
17.6	201.11	
18.1	201.12.1	
18.2	201.12.4	

19.1	201.7, 201.12.2.101, 201.102, 206	
19.2	201.7, 201.12.2.101, 201.102, 206, 211	
20.1	211	The part relating to manufacturing is not addressed
20.2	211	The part relating to manufacturing is not addressed
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7	
21.5	—	
a)	201.7	The part relating to authorized representative is not addressed
b)	201.7.2.17.101 a)	
d)	201.7.2.17.101 a)	
e)	201.7	
f)	201.7.2.17.101 b)	
i)	201.7.2.101 a), 211	
j)	201.7.2.101 a), 211	
k)	201.7.2.101 b)	
l)	201.7	
21.6	201.7, 201.7.2.17.101 a)	
21.7	—	
a)	201.7.9.1	
d)	201.7.2.17.101 b), 201.7.9.2.1.102	
h)	201.7.9.2	
i)	201.7.9.2.2.101, 211	
k)	201.7.9.2.8.101, 201.7.9.2.9.101, 201.7.9.2.14.101, 201.16, 201.101.2	
l)	201.7.9.2.8.101, 201.7.9.2.9.101	
n)	201.16	
p)	201.7.9.2.12, 201.11, 211	
q)	201.7	
21.8	201.7	
21.9	—	
a)	211	
b)	211	

f)	201.12.1, 211	

Annex DD
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP)[9] and the IEC Electropedia[10] provide access to many of these terms and definitions.

Term	Source
ACCESSORY	IEC 60601-1:2005, 3.3
ACCOMPANYING DOCUMENT	IEC 60601-1:2005, 3.4
ACKNOWLEDGED	IEC 60601-1-8:2006+AMD1:2012, 3.37
AIRWAY PRESSURE (P_{aw})	ISO 80601-2-12:—, 201.3.201
ALARM CONDITION	IEC 60601-1-8:2006+AMD1:2012, 3.1
ALARM LIMIT	IEC 60601-1-8:2006, 3.3
ALARM OFF	IEC 60601-1-8:2006, 3.4
ALARM PAUSED	IEC 60601-1-8:2006, 3.5
ALARM SIGNAL	IEC 60601-1-8:2006, 3.9
ALARM SYSTEM	IEC 60601-1-8:2006, 3.11
APPLIED PART	IEC 60601-1:2005, 3.8
AUDIO OFF	IEC 60601-1-8:2006, 3.12
AUDIO PAUSED	IEC 60601-1-8:2006, 3.13
BASIC SAFETY	IEC 60601-1:2005, 3.10
BODY TEMPERATURE PRESSURE, SATURATED	ISO 80601-2-74:2017, 201.3.203
BIOCOMPATIBILITY	ISO 18562-1:2017, 3.2
BREATHING SYSTEM FILTER	ISO 23328-2:2002, 3.1
BSF	ISO 23328-2:2002, 3.1
BTPS	ISO 80601-2-74:2017, 201.3.203
CLEANING	ISO 17664:2017, 3.1
CLEARLY LEGIBLE	IEC 60601-1:2005+AMD1:2012, 3.15
DELIVERED VOLUME (V_{del})	ISO 80601-2-12: —, 201.3.202
DISINFECTION	ISO 17664:2017, 3.3
DISTRIBUTED ALARM SYSTEM	IEC 60601-1-8:2006, 3.17
ENCLOSURE	IEC 60601-1:2005, 3.26
ESSENTIAL PERFORMANCE	IEC 60601-1:2005+AMD1:2012, 3.27
ESSENTIAL PRINCIPLES	ISO 16142-1:2016, 3.3

[9] Available at: https://www.iso.org/obp/ui/#home

[10] Available at http://www.electropedia.org/

Term	Source
ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE	ISO 16142-1:2016, 3.3
EXHAUST PORT	ISO 80601-2-12:—, 201.3.204
EXPECTED SERVICE LIFE	IEC 60601-1:2005+AMD1:2012, 3.28
FALSE POSITIVE ALARM CONDITION	IEC 60601-1-8:2006, 3.21
FUNCTIONAL CONNECTION	IEC 60601-1:2005, 3.33
FLOW-DIRECTION-SENSITIVE COMPONENT	ISO 80601-2-12: —, 201.3.205
FRESH GAS	ISO 80601-2-12: —, 201.3.206
GAS INTAKE PORT	ISO 80601-2-12: —, 201.3.207
GAS PATHWAY	ISO 18562-1:2017, 3.5
GAS RETURN PORT	ISO 80601-2-12: —, 201.3.209
HARM	IEC 60601-1:2005, 3.38
HAZARD	IEC 60601-1:2005, 3.39
HAZARDOUS SITUATION	IEC 60601-1:2005, 3.40
HEALTHCARE PROFESSIONAL	201.3.201
HOME HEALTHCARE ENVIRONMENT	IEC 60601-1-11:2015, 3.2
HME (HEAT AND MOISTURE EXCHANGER)	ISO 9360-1:2000, 3.1
HUMIDIFIER	IEC 60601-2-74:2017, 201.3.208
IMMUNITY	IEC 60601-1-2:2014, 3.8
INSPIRATORY TIME (T_I)	ISO 4135:2001, 3.4.13
INTENDED USE	IEC 60601-1:2005+AMD1:2012, 3.44
INTELLIGENT ALARM SYSTEM	IEC 60601-1-8:2006, 3.24
INTERNAL ELECTRICAL POWER SOURCE	IEC 60601-1:2005, 3.45
LAY	IEC 60601-1-11:2015, 3.3
MAINS CONNECTOR	IEC 60601-1:2005, 3.48
MANUFACTURER	IEC 60601-1:2005, 3.55
MANUAL VENTILATION PORT	ISO 80601-2-12:2011, 201.3.213
MASK	ISO 17510:2015, 3.4
MAXIMUM LIMITED PRESSURE ($P_{LIM\ max}$)	ISO 80601-2-72:2015, 201.3.212
MAXIMUM WORKING PRESSURE	ISO 80601-2-12:—, 201.3.214
MECHANICAL HAZARD	IEC 60601-1:2005, 3.61
ME EQUIPMENT (MEDICAL ELECTRICAL EQUIPMENT)	IEC 60601-1:2005, 3.63
ME SYSTEM (MEDICAL ELECTRICAL SYSTEM)	IEC 60601-1:2005, 3.64
MEDICAL GAS PIPELINE SYSTEM	ISO 7396-1:2016, 3.36
MODEL OR TYPE REFERENCE	IEC 60601-1:2005, 3.66
MONITORING EQUIPMENT	ISO 80601-2-72:2015, 201.3.213
NOMINAL <VALUE>	IEC 60601-1:2005, 3.69
NORMAL CONDITION	IEC 60601-1:2005, 3.70

Term	Source
NORMAL USE	IEC 60601-1:2005, 3.71
OPERATOR	IEC 60601-1:2005, 3.73
OPERATOR-EQUIPMENT INTERFACE	IEC 60601-1-6:2010, 3.1
PATIENT	IEC 60601-1:2005+AMD1:2012, 3.76
PATIENT-CONNECTION PORT	ISO 80601-2-12:—, 201.3.217
PEEP	ISO 4135:2001, 3.3.11
PHYSIOLOGICAL ALARM CONDITION	IEC 60601-1-8:2006+AMD1:2012, 3.31
POSITIVE END-EXPIRATORY PRESSURE	ISO 4135:2001, 3.3.11
PRIMARY OPERATING FUNCTION	IEC 62366-1:2015, 3.11
PROCEDURE	IEC 60601-1:2005+AMD1:2012, 3.88
PROCESS	IEC 60601-1:2005+AMD1:2012, 3.89
PROCESSING	ISO 17664:2017, 3.8
PEMS (PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS)	IEC 60601-1:2005, 3.90
PROTECTION DEVICE	ISO 80601-2-72:2015, 201.3.216
RATED <VALUE>	IEC 60601-1:2005, 3.97
REBREATHING	ISO 4135:2001, 4.1.4
RESPIRATORY IMPAIRMENT	201.3.202
RESPIRATORY INSUFFICIENCY	201.3.203
RESPONSIBLE ORGANIZATION	IEC 60601-1:2005, 3.101
RISK	IEC 60601-1:2005, 3.102
RISK CONTROL	IEC 60601-1:2005+AMD1:2012, 3.105
RISK MANAGEMENT	IEC 60601-1:2005+AMD1:2012, 3.107
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